

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

AVENTIS PHARMACEUTICALS INC. and  
SANOFI-AVENTIS US LLC,

Plaintiffs,

v.

BARR LABORATORIES, INC.

Defendant.

C.A. No. 06-286 (GMS)

**OPENING BRIEF IN SUPPORT OF BARR LABORATORIES' RULE 12(b)(6)  
MOTION TO DISMISS PLAINTIFFS' WILLFUL INFRINGEMENT CLAIMS  
OR, ALTERNATIVELY, TO BIFURCATE AND STAY DISCOVERY ON THEM**

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Dated: May 31, 2006

## TABLE OF CONTENTS

	Page
I. INTRODUCTION .....	1
II. NATURE AND STAGE OF PROCEEDINGS.....	2
III. SUMMARY OF ARGUMENT .....	2
IV. FACTUAL BACKGROUND .....	3
V. ARGUMENT.....	4
A. This Court Should Dismiss Plaintiffs' Willful Infringement Claims Under Controlling Federal Circuit Precedent.....	4
B. Alternatively, This Court Should Bifurcate And Stay Discovery On Plaintiffs' Willful Infringement Claims To Avoid Prejudice To Barr .....	7
VI. CONCLUSION.....	10

## TABLE OF AUTHORITIES

## FEDERAL CASES

<i>Amsted Indus. Inc. v. National Castings Inc.</i> , 16 U.S.P.Q.2d 1737 (N.D. Ill. 1990) .....	10
<i>Aventis Pharma Deutschland GmbH v. Cobalt Pharms., Inc.</i> , 355 F. Supp. 2d 586 (D. Mass. 2005) .....	7
<i>Aventis Pharma Deutschland GmbH v. Lupin Ltd.</i> , 409 F. Supp. 2d 722 (E.D. Va. 2006) .....	7
<i>Bandai Am. Inc. v. Bally Midway Mfg. Co.</i> , 775 F.2d 70 (3d Cir. 1985).....	8
<i>Celgene Corp. v. Teva Pharms. USA, Inc.</i> , 412 F. Supp. 2d 439 (D.N.J. 2006) .....	7
<i>Eli Lilly &amp; Co. v. Medtronic, Inc.</i> , 496 U.S. 661 (1990).....	4, 6
<i>Glaxo Group Ltd. v. Apotex, Inc.</i> , 268 F. Supp. 2d 1013 (N.D. Ill. 2003) .....	5
<i>Glaxo Group Ltd. v. Apotex, Inc.</i> , 376 F.3d 1339 (Fed. Cir. 2004).....	<i>passim</i>
<i>Lemelson v. Apple Computer Inc.</i> , 28 U.S.P.Q.2d 1412 (D. Nev. 1993) .....	9
<i>Novopharm Ltd. v. TorPharm, Inc.</i> , 181 F.R.D. 308 (E.D.N.C. 1998) .....	9, 10
<i>Oatway v. Am. Int'l Group, Inc.</i> , 325 F.3d 184 (3d Cir. 2003).....	5
<i>Pfizer Inc. v. Novopharm Ltd.</i> , 57 U.S.P.Q.2d 1442 (N.D. Ill. 2000) .....	3, 9, 10
<i>Princeton Biochems., Inc. v. Beckman Instruments, Inc.</i> , 180 F.R.D. 254 (D.N.J. 1997).....	9, 10
<i>Quantum Corp. v. Tandon Corp.</i> , 940 F.2d 642 (Fed. Cir. 1991).....	3, 8
<i>In re Recombinant DNA Tech. Patent &amp; Contract Litig.</i> , 30 U.S.P.Q.2d 1881 (S.D. Ind. 1994) .....	8, 10

<i>Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.</i> , 231 F.3d 1339 (Fed. Cir. 2000).....	6
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### DOCKETED CASES

<i>aaiPharma, Inc. v. Barr Labs., Inc.</i> , No. 7:01-CV-150-F1, Order (E.D.N.C. Sept. 9, 2002).....	9
<i>Allergan, Inc. v. Alcon Inc.</i> , C.A. No. 04-968 (GMS), 2005 WL 3971927 (D. Del. July 26, 2005).....	1, 6, 7
<i>Allergan, Inc. v. Pharmacia Corp.</i> , No. Civ. A 01-141-SLR, 2002 WL 1268047 (D. Del. May 22, 2002).....	9
<i>Aptargroup, Inc. v. Owens-Illinois, Inc.</i> , No. 02 C 5058, 2003 WL 21557632 (N.D. Ill. July 3, 2003) .....	8
<i>ArthroCare Corp. v. Smith &amp; Nephew, Inc.</i> , C.A. No. 01-504-SLR, Mem. Order (D. Del. Nov. 27, 2002) .....	9
<i>Eli Lilly &amp; Co. v. Barr Labs., Inc.</i> , No. IP 96-0491-C-B/S, Order (S.D. Ind. Oct. 29, 1998) .....	9
<i>Eli Lilly &amp; Co. v. Barr Labs., Inc.</i> , No. 1:02-CV-1844-SEB, Order (S.D. Ind. Apr. 1, 2004).....	8-9
<i>In re '318 Patent Infringement Litig.</i> , C.A. No. 05-356 (KAJ), Hearing Tr. (D. Del. Mar. 3, 2006) .....	6, 7
<i>Integral Resources (PVT) Ltd. v. Istil Group, Inc.</i> , No. 03-904 (GMS), 2004 WL 2758672 (D. Del. Dec. 2, 2004) .....	5
<i>Item Dev. AB v. Sicor Inc.</i> , Nos. Civ. 05-336-SLR, Civ. 05-337-SLR, 2006 WL 891032 (D. Del. Mar. 31 2006).....	2, 6, 7
<i>Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.</i> , C.A. No. 3:04-1689 (MLC), Hearing Tr. (D.N.J. Apr. 18, 2005).....	7
<i>Ortho-McNeil v. Teva Pharms. USA, Inc.</i> , No. 02-2794 (GEB), Mem. Op. (D.N.J. Jan. 28, 2003).....	9
<i>Sage Prods., Inc. v. Devon Indus., Inc.</i> , No. CV 93-2404 RG(CTX), 1994 WL 791601 (C.D. Cal. Jan. 25, 1994) .....	8
<i>SmithKline &amp; French Labs., Ltd. v. Teva Pharms., USA, Inc.</i> , C.A. No. 05-197-GMS, Hearing Tr. (D. Del. July 28, 2005) .....	7

<i>St. Clair Intellectual Prop. Consultants, Inc. v. Sony Corp.</i> , No. Civ. A. 01-557-JJF, 2002 WL 1901268 (D. Del. Aug. 16, 2002) .....	3, 9
<i>UCB Societe Anonyme v. Mylan Labs., Inc.</i> , No. 1:04-CV-683-WSD, 2006 WL 486895 (N.D. Ga. Feb. 28, 2006).....	6-7
<i>United States Gypsum Co. v. National Gypsum Co.</i> , No. 89 C 7533, 1994 WL 74989 (N.D. Ill. Mar. 10, 1994) .....	9

## STATUTES & REGULATIONS

21 U.S.C. § 355 .....	3
21 U.S.C. § 355(b)(1) .....	3
21 U.S.C. § 355(j)(1) .....	3
21 U.S.C. § 355(j)(2) .....	3
21 U.S.C. § 355(j)(2)(A)(vii) .....	3
21 U.S.C. § 355(j)(2)(A)(vii)(IV) .....	4
21 U.S.C. § 355(j)(7)(A)(iii) .....	3
35 U.S.C. § 156 .....	3
35 U.S.C. § 271(e) .....	3
35 U.S.C. § 271(e)(2) .....	<i>passim</i>
35 U.S.C. § 271(e)(4) .....	5, 6
35 U.S.C. § 285 .....	5, 6
Fed. R. Civ. P. 12(b)(6) .....	2, 4
Fed. R. Civ. P. 42(b) .....	1, 2, 7, 8
Pub. L. No. 98-417, 98 Stat. 1585 (1984) .....	3
21 C.F.R. § 314.94(a)(12)(i)(A)(4) .....	4

## I. INTRODUCTION.

Numerous courts, including this Court, have followed controlling Federal Circuit precedent and dismissed willful infringement claims by patentees against drug companies like Defendant Barr Laboratories, Inc. They did so because, according to the Federal Circuit, a claim for willful infringement cannot, as a matter of law, be based solely on the filing of an Abbreviated New Drug Application (“ANDA”). See *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004); see also *Allergan, Inc. v. Alcon Inc.*, C.A No. 04-968 (GMS), 2005 WL 3971927 (D. Del. July 26, 2005) (Sleet, J.) (striking patentee’s willful infringement claims against “paper NDA” applicant) (Ex. 2). Plaintiffs here have alleged only one basis for their willful infringement claims – Barr’s ANDA filing. This allegation is insufficient as a matter of law. Plaintiffs have alleged no facts entitling them to relief for willful infringement. Accordingly, their willful infringement claims must be dismissed.

Alternatively, if this Court denies Barr’s motion to dismiss, it should bifurcate and stay discovery on Plaintiffs’ willful infringement claims under Fed. R. Civ. P. 42(b). A defendant in a patent infringement case can suffer severe prejudice when defending willful infringement claims because it is frequently forced to choose between asserting an advice-of-counsel defense to willful infringement, which requires it to waive attorney-client privilege, or foregoing the defense. To prevent this prejudice and conserve judicial resources, courts frequently bifurcate willful infringement claims from liability under Rule 42(b). Barr faces this prejudice here. If this Court allows Plaintiffs’ willful infringement claims to remain in the case, it should order bifurcation and stay discovery on them in order to avoid prejudice to Barr and to promote judicial economy.

## II. NATURE AND STAGE OF PROCEEDINGS.

This is a patent infringement case brought by Plaintiffs Aventis Pharmaceuticals Inc. (“Aventis”) and Sanofi-Aventis US LLC (“Sanofi-Aventis” and, together with Aventis, “Plaintiffs”) against Defendant Barr Laboratories, Inc. (“Barr”). (*See* D.I. 1, Compl.). Plaintiffs sued Barr on May 2, 2006, alleging that Barr has infringed two patents Aventis owns, U.S. Patent Nos. 5,976,573 (“the ‘573 patent”) and 6,143,329 (“the ‘329 patent”). According to Plaintiffs, Barr committed infringement under 35 U.S.C. § 271(e)(2) by filing an ANDA seeking approval to market a generic triamcinolone acetonide nasal spray product prior to the expiration of the ‘573 and ‘329 patents. (D.I. 1, Compl. ¶ 14).

Barr counterclaimed on May 22, 2006, seeking declarations that the patents-in-suit are invalid or not infringed. (*See* D.I. 6, Answer).

## III. SUMMARY OF ARGUMENT.

1. Plaintiffs’ willful infringement contentions are based solely on Plaintiffs’ allegation that Barr infringed the ‘573 and ‘329 patents under 35 U.S.C. § 271(e)(2) by filing an ANDA that challenges the validity, enforceability and/or infringement of those patents. (*See* D.I. 1, Compl. ¶¶ 14, 15). But under controlling Federal Circuit caselaw, “the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement . . . .” *Glaxo*, 376 F.3d at 1350-51. Accordingly, Plaintiffs’ willful infringement claims should be dismissed under Fed. R. Civ. P. 12(b)(6) for failure to state a claim. *See, e.g., Item Dev. AB v. Sicor Inc.*, Nos. Civ. 05-336-SLR, Civ. 05-337-SLR, 2006 WL 891032, at \*2 (D. Del. Mar. 31, 2006) (Robinson, J.) (dismissing willful infringement claims against ANDA applicant) (Ex. 10).

2. In the alternative, this Court should bifurcate and stay discovery on Plaintiffs’ willful infringement claims under Fed. R. Civ. P. 42(b). Absent bifurcation, Barr will

be prejudiced by being forced to choose between waiving privilege to assert an advice-of-counsel defense to Plaintiffs' willful infringement claims, or foregoing the defense. *See Quantum Corp. v. Tandon Corp.*, 940 F.2d 642, 643-44 (Fed. Cir. 1991); *St. Clair Intellectual Prop. Consultants, Inc. v. Sony Corp.*, No. Civ. A. 01-557-JJF, 2002 WL 1901268, at \*2 (D. Del. Aug. 16, 2002) (Ex. 15). In addition, bifurcation will promote judicial economy by deferring, and potentially avoiding altogether, the need to address willful infringement until after the liability issues have been decided. *See Pfizer Inc. v. Novopharm Ltd.*, 57 U.S.P.Q.2d 1442, 1444 (N.D. Ill. 2000).

#### IV. FACTUAL BACKGROUND.

Plaintiffs' case is grounded in the Hatch-Waxman Amendments to the Federal Food Drug and Cosmetic Act ("FFDCA"). *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Under the FFDCA, as amended, a company seeking approval to market a drug that has not previously been approved must file with the U.S. Food and Drug Administration ("FDA") a New Drug Application ("NDA") which contains studies showing the proposed drug product is safe and effective. 21 U.S.C. § 355(b)(1). The NDA must include, among other things, any patent that "claims the drug for which the applicant submitted the application . . . ." *Id.* FDA publishes the patent information in connection with the NDA in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 U.S.C. § 355(b)(1), -(j)(7)(A)(iii).

A company seeking approval of a generic version of an already approved NDA drug may file an ANDA that relies on the safety and efficacy studies of the NDA drug. *Id.* § 355(j)(1), -(j)(2). To do so, the ANDA applicant must, among other things, submit a "certification" for each patent listed in the Orange Book in connection with the brand name drug. *Id.* § 355(j)(2)(A)(vii). An ANDA applicant seeking to obtain approval prior to expiration of a

listed patent must (with certain exceptions) submit a “paragraph IV” certification, which states that the patent is invalid, unenforceable and/or will not be infringed by the proposed ANDA product. *Id.* § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4). A paragraph IV certification is considered a “highly artificial act of infringement” under 35 U.S.C. § 271(e)(2), the “very limited and technical purpose” of which is “to permit patent holders to bring suit against generic companies despite the fact that the generic companies have not yet infringed the patents at issue.” *Glaxo*, 376 F.3d at 1349, 1351 (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676, 678 (1990)).

Sanofi-Aventis holds an approved NDA No. 20-468 for NASACORT AQ<sup>®</sup>, a nasal spray containing triamcinolone acetonide as the active ingredient, which is used to treat allergic rhinitis. (D.I. 1, Compl. ¶ 10). The ‘573 and ‘329 patents, owned by Aventis, are listed in the Orange Book in connection with NASACORT AQ<sup>®</sup>. (*Id.* ¶¶ 8, 9, 12).

In 2005, Barr filed ANDA No. 78-104, seeking approval to market a generic triamcinolone acetonide nasal spray and referencing the NASACORT AQ<sup>®</sup> NDA. (*Id.* ¶ 11). Barr’s ANDA contains paragraph IV certifications to the ‘573 and ‘329 patents. (*Id.* ¶ 13). Barr duly notified Plaintiffs of its paragraph IV certifications in March 2006. (*Id.* ¶¶ 11-13). Plaintiffs responded by initiating this patent infringement action under 35 U.S.C. § 271(e)(2). (*Id.* ¶ 14). Plaintiffs’ Complaint includes a claim that Barr’s filing of its ANDA with the paragraph IV certifications constitutes willful infringement. (*Id.* ¶ 15).

## V. ARGUMENT.

### A. This Court Should Dismiss Plaintiffs’ Willful Infringement Claims Under Controlling Federal Circuit Precedent.

The Court may grant a motion to dismiss under Fed. R. Civ. P. 12(b)(6) if, “accepting all well-pleaded allegations in the complaint as true, and viewing them in the light

most favorable to the plaintiff, plaintiff is not entitled to relief.” *Oatway v. Am. Int’l Group, Inc.*, 325 F.3d 184, 187 (3d Cir. 2003) (quotations and citation omitted). While the court must accept well-pleaded allegations as true, “[t]he court need not accept as true unsupported conclusions and unwarranted inferences.” *Integral Resources (PVT) Ltd. v. Istil Group, Inc.*, No. 03-904 (GMS), 2004 WL 2758672, at \*2 (D. Del. Dec. 2, 2004) (quotations and citation omitted) (Ex. 9).

Here, Plaintiffs’ willful infringement claims are based only on their allegation that Barr filed an ANDA with paragraph IV certifications to the ‘573 and ‘329 patents. (*See* D.I. 1, Compl. ¶¶ 14, 15). Under Federal Circuit caselaw, Plaintiffs’ allegations are insufficient as a matter of law: “the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney’s fees pursuant to 35 U.S.C. § 271(e)(4).” *Glaxo*, 376 F.3d at 1350-51.

In *Glaxo*, the Federal Circuit rejected the district court’s conclusion that an ANDA applicant could be liable for willful infringement based on the ANDA filing. The patentee in *Glaxo* presented evidence that the defendant willfully infringed the patent based on its ANDA filing, by failing to get an opinion of counsel and admitting infringement in its own patent application. *See Glaxo Group Ltd. v. Apotex, Inc.*, 268 F. Supp. 2d 1013, 1033-35 (N.D. Ill. 2003). This evidence led the district court to conclude that the defendant was liable for attorney’s fees under 35 U.S.C. § 285 due to willful infringement. *Id.* Yet, despite this evidence – evidence that the Federal Circuit did not discredit – the Federal Circuit held that the district court clearly erred in finding that the patentee could recover § 285 attorney’s fees for willful infringement. *Glaxo*, 376 F.3d at 1349-51.

The Federal Circuit reasoned that “the act of filing an ANDA constitutes a ‘highly artificial’ act of infringement under 35 U.S.C. § 271(e)(2) . . . [which] gives rise to only a limited

set of statutorily-defined consequences . . . .” *Id.* (quoting *Eli Lilly & Co.*, 496 U.S. at 678). While the Patent Act permits an award of enhanced damages for willful infringement in ordinary patent infringement cases, § 271(e)(4) expressly limits the monetary award a patentee may obtain for infringement under § 271(e)(2) to only attorney’s fees under § 285. *Glaxo*, 376 F.3d at 1349-50 (quoting § 271(e)(4)). Furthermore, the Federal Circuit “has limited what types of conduct may give rise to an award of attorney’s fees for purposes of Section 271(e)(4).” *Glaxo*, 376 F.3d at 1350. Specifically, “a baseless and ‘wholly unjustified’ paragraph IV certification in an ANDA filing, when combined with litigation misconduct” may give rise to a finding of an exceptional case under § 285. *Glaxo*, 376 F.3d at 1350 (citing *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1346 (Fed. Cir. 2000)). But ordinary evidence of willful infringement, after *Glaxo*, does not. *Id.* at 1350-51 (rejecting district court’s assessment of attorney’s fees based on ANDA applicant’s willful infringement). Accordingly, “[t]he district court erred in hanging a finding of willfulness on such a special-purpose peg” as § 271(e)(2)’s artificial act of infringement. *Glaxo*, 376 F.3d at 1351.

Since the *Glaxo* opinion, numerous courts, including this one, have held that a patentee cannot sustain willful infringement claims based on infringement under § 271(e)(2). *See Allergan*, 2005 WL 3971927, at \*2 (Sleet, J.) (holding that paper NDA filing with “allegedly baseless” paragraph IV certification “cannot be considered willful” and therefore the “complaint does not state any basis under which [the patentee] could state a claim for willful infringement”); *Item Dev.*, 2006 WL 891032, at \*2 (Robinson, J.) (dismissing willful infringement claims against ANDA applicant); *In re ‘318 Patent Infringement Litig.*, C.A. No. 05-356 (KAJ), Hearing Tr. at \*5-\*7 (D. Del. Mar. 3, 2006) (Jordan, J.) (dismissing willful infringement claims against ANDA applicants based on *Glaxo* and *Allergan* decisions, among others) (Ex. 8); *UCB Societe Anonyme*

*v. Mylan Labs., Inc.*, No. 1:04-CV-683-WSD, 2006 WL 486895, at \*2 (N.D. Ga. Feb. 28, 2006) (dismissing willful infringement claims against ANDA applicants) (Ex. 16); *Celgene Corp. v. Teva Pharms. USA, Inc.*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006) (same); *Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, 409 F. Supp. 2d 722, 730-31 (E.D. Va. 2006) (same); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, C.A. No. 3:04-1689 (MLC), Hearing Tr. at \*8-\*10 (D.N.J. Apr. 18, 2005) (same) (Ex. 11); *Aventis Pharma Deutschland GmbH v. Cobalt Pharms., Inc.*, 355 F. Supp. 2d 586, 592-93 (D. Mass. 2005) (same); *but see SmithKline & French Labs., Ltd. v. Teva Pharms., USA, Inc.*, C.A. No. 05-197-GMS, Hearing Tr. at \*8-\*9 (D. Del. July 28, 2005) (Sleet, J.) (reserving decision, for summary judgment, on whether patentee's willful infringement claims could be sustained against ANDA applicant) (Ex. 14).

Plaintiffs' complaint is no different from the complaints in *Glaxo*, *Allergan* or the other cases: their willful infringement claims depend solely on Barr's ANDA filing with the paragraph IV certifications. Moreover, Plaintiffs do not even allege that Barr's paragraph IV certifications were baseless or "wholly unjustified," let alone that Barr has engaged in litigation misconduct. Accordingly, Plaintiffs' complaint sets forth no facts that would entitle Plaintiffs to any relief for alleged willful infringement. Plaintiffs' willful infringement claims should be dismissed. *Glaxo*, 376 F.3d at 1351; *Allergan*, 2005 WL 3971927, at \*2; *Item Dev.*, 2006 WL 891032, at \*2; *'318 Patent Litig.*, C.A. No. 05-356, Hearing Tr. at \*5-\*7.

**B. Alternatively, This Court Should Bifurcate And Stay Discovery On Plaintiffs' Willful Infringement Claims To Avoid Prejudice To Barr.**

In the event that this Court denies Barr's motion to dismiss Plaintiffs' willful infringement claims, Barr requests, alternatively, that this Court order bifurcation and stay discovery on those claims until after liability is decided. Under Fed. R. Civ. P. 42(b), this Court has discretion to order separate trials on claims "in furtherance of convenience or to avoid

prejudice, or when separate trials will be conducive to expedition and economy . . . .” Fed. R. Civ. P. 42(b); *Bandai Am. Inc. v. Bally Midway Mfg. Co.*, 775 F.2d 70, 74 (3d Cir. 1985) (affirming district court’s discretion to bifurcate under Rule 42(b)).

Bifurcation and a stay of discovery of Plaintiffs’ willful infringement claims is warranted in this case because it will prevent severe prejudice to Barr. Specifically, absent bifurcation, Barr will face an impossible dilemma, forced to choose between waiving attorney-client privilege by asserting an advice-of-counsel defense to Plaintiffs’ willful infringement claims or foregoing the defense at the risk of a willful infringement finding. *See Quantum Corp.*, 940 F.2d at 643-44. The Federal Circuit has cautioned that

[a]n accused infringer should not, . . . without the trial court’s careful consideration, be forced to choose between waiving the privilege in order to protect itself from a willfulness finding, in which case it may risk prejudicing itself on the question of liability, and maintaining the privilege, in which case it may risk being found to be a willful infringer if liability is found.

*Id.* See also *In re Recombinant DNA Tech. Patent & Contract Litig.*, 30 U.S.P.Q.2d 1881, 1900 (S.D. Ind. 1994) (ordering bifurcation to avoid prejudice “that could result if [defendants] were forced to provide their opposition with a ‘detailed work product road map’” to their liability arguments).

Thus, for defendants faced with this so-called “*Quantum*” dilemma, the Federal Circuit recommends separate trials on liability and willful infringement. *Quantum*, 940 F.2d at 644; see also *Aptargroup, Inc. v. Owens-Illinois, Inc.*, No. 02 C 5058, 2003 WL 21557632, at \*1 (N.D. Ill. July 3, 2003) (“The Federal Circuit encourages bifurcation when a party is faced with . . . the ‘Quantum dilemma’ . . . .”) (Ex. 4); *Sage Prods., Inc. v. Devon Indus., Inc.*, No. CV 93-2404 RG(CTX), 1994 WL 791601, at \*2 (C.D. Cal. Jan. 25, 1994) (same) (Ex. 13). And district courts, including courts in this District, have followed that recommendation. *See, e.g., Eli Lilly*

& Co. v. Barr Labs., Inc., No. 1:02-CV-1844-SEB, Order (S.D. Ind. Apr. 1, 2004) (granting bifurcation and discovery stay on willful infringement claims in ANDA case) (Ex. 6); *ArthroCare Corp. v. Smith & Nephew, Inc.*, C.A. No. 01-504-SLR, Mem. Order, at \*3 (D. Del. Nov. 27, 2002) (Robinson, J.) (same in non-ANDA case) (Ex. 5); *St. Clair*, 2002 WL 1901268, at \*2 (Farnan, J.) (same); *Allergan Inc. v. Pharmacia Corp.*, No. Civ. A. 01-141-SLR, 2002 WL 1268047, at \*2 n.1 (D. Del. May 17, 2002) (Robinson, J.) (same) (Ex. 3).<sup>1</sup>

Like these defendants, Barr faces the same prejudice absent bifurcation and a discovery stay. Facing Plaintiffs' willful infringement claims, Barr will be forced to choose between waiving privilege to assert an advice-of-counsel defense and foregoing the defense. Either way, Barr is placed at a distinct disadvantage. In these circumstances, bifurcation is warranted to prevent prejudicing Barr.

Bifurcation of Plaintiffs' willful infringement claims is also appropriate because it will promote judicial efficiency and economy. If Barr succeeds on the liability phase, the Court need not decide the issue of willful infringement. *See Lemelson v. Apple Computer Inc.*, 28 U.S.P.Q.2d 1412, 1423 (D. Nev. 1993) ("[W]illfulness is not part of the liability finding, and the issue need not be reached if the patent is found invalid or not infringed."); *Pfizer*, 57 U.S.P.Q.2d at 1445 (same). Moreover, the Court will not need to hash out potential disputes concerning the scope of any waiver in determining the discovery to which Plaintiffs are entitled. Courts have concluded that potential efficiencies such as these counsel in favor of bifurcation. *See id.* (bifurcating willfulness, despite finding no immediate *Quantum* dilemma, because a finding of

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<sup>1</sup> *Accord Ortho-McNeil v. Teva Pharms. USA*, No. 02-2794 (GEB), Mem. Op., at \*7-\*8 (D.N.J. Jan. 28, 2003) (same in ANDA case) (Ex. 12); *aaiPharma, Inc. v. Barr Labs., Inc.*, No. 7:01-CV-150-F1, Order (E.D.N.C. Sept. 9, 2002) (same) (Ex. 1); *Eli Lilly & Co. v. Barr Labs., Inc.*, No. IP 96-0491-C-B/S, Order, at \*2-\*3 (S.D. Ind. Oct. 29, 1998) (same) (Ex. 7); *Novopharm Ltd. v. TorPharm, Inc.*, 181 F.R.D. 308, 311-12 (E.D.N.C. 1998) (same in non-ANDA case); *Princeton Biochems., Inc. v. Beckman Instruments, Inc.*, 180 F.R.D. 254, 260 (D.N.J. 1997) (same); *United States Gypsum Co. v. Nat'l Gypsum Co.*, No. 89 C 7533, 1994 WL 74989, at \*2 (N.D. Ill. Mar. 10, 1994) (same) (Ex. 17).

no liability would obviate need for willfulness discovery and trial); *Novopharm*, 181 F.R.D. at 312 (observing that bifurcation of willfulness would defer discovery and trial until preliminary liability issues were decided); *Recombinant DNA*, 30 U.S.P.Q.2d at 1901 (ordering bifurcation and stay in part to defer issues concerning scope of discovery).

Finally, bifurcation is appropriate because there will be little overlap between the liability and willfulness issues. “Liability is a function of the objective ‘validity’ of the patent, while willful infringement is a function of the defendant’s “subjective intent and belief.” *Pfizer*, 57 U.S.P.Q.2d at 1444. Here, the liability issues will focus primarily on technical and legal matters concerning the teachings of the prior art and claim construction. Willfulness issues, in contrast, will depend on Barr’s state of mind at the time of the alleged infringement. Thus, any overlap of proof on liability and willfulness will be minimal or non-existent. *Id.* at 1445; *see also Novopharm*, 181 F.R.D. at 312 (observing that there is “no significant overlap” between invalidity and willfulness); *Princeton Biochems.*, 180 F.R.D. at 258 (same); *Amsted Indus. Inc. v. Nat’l Castings Inc.*, 16 U.S.P.Q.2d 1737, 1739-40 (N.D. Ill. 1990) (same).

In sum, this Court should order bifurcation and a discovery stay on Plaintiffs’ willful infringement claims because bifurcation would prevent severe prejudice to Barr and promote judicial economy.

**VI. CONCLUSION.**

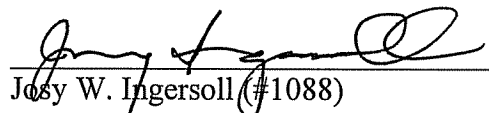
Barr respectfully requests that this Court dismiss Plaintiffs' willful infringement claims for failure to state a claim or, alternatively, to bifurcate and stay discovery on them to avoid prejudicing Barr and promote judicial economy.

Dated: May 31, 2006

Respectfully submitted,

BARR LABORATORIES, INC.

By:

  
Josy W. Ingersoll (#1088)  
Karen L. Pascale (#2903)  
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*Attorneys for Defendant Barr Laboratories, Inc.*

**CERTIFICATE OF SERVICE**

I, Josy W. Ingersoll, Esquire, hereby certify that on May 31, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on May 31, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

**BY EMAIL**

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\_\_\_\_\_  
Josy W. Ingersoll (#1088)

EX. 1

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NORTH CAROLINA  
SOUTHERN DIVISION

FILED

SEP 9 2002

DAVID J. CLEGG  
U.S. DISTRICT COURT  
EASTERN DISTRICT OF NORTH CAROLINA

aaIPHARMA, INC.,  
Plaintiff,

v.

BARR LABORATORIES, INC.,  
PAR PHARMACEUTICAL, INC., DR.  
REDDY'S LABORATORIES, LTD., and  
REDDY-CHEMINOR, INC.,  
Defendants.

Civil Action No. 7:01-CV-150-F1

Exhibits #27, 25, 4

aaIPHARMA, INC.,  
Plaintiff,

v.

BARR LABORATORIES, INC.,  
PAR PHARMACEUTICAL, INC., DR.  
REDDY'S LABORATORIES, LTD., and  
REDDY-CHEMINOR, INC.,  
Defendants.

Civil Action No. 7:01-CV-202-F1

aaIPHARMA, INC.,  
Plaintiff,

v.

BARR LABORATORIES, INC.,  
PAR PHARMACEUTICAL, INC., DR.  
REDDY'S LABORATORIES, LTD., and  
REDDY-CHEMINOR, INC.,  
Defendants.

Civil Action No. 7:01-CV-208-F1

ORDER

This matter is before the court upon the following motions:<sup>1</sup>

<sup>1</sup> "DE # \_\_\_" refers to the docket number of the document in the lead case file,  
No. 7:01-CV-150-F1

86

(1) by Barr Laboratories, Inc. ("Barr") (DE # 54)<sup>2</sup>

- (a) to bifurcate aaiPHARMA's (DE-54-1)
  - (i) willful infringement and damages claim from
  - (ii) the patent issues of validity, enforceability and infringement; and
- (b) to stay discovery as to the willful infringement and damages claims. (DE #54)

(2) by aaiPHARMA

- (a) to bifurcate (DE # 63-1)
  - (i) all patent related claims, defenses and counter-claims from
  - (ii) Barr's state law counter-claims; and
- (b) to stay discovery as to the state law counter-claims (DE #63-2).

The issues have been fully briefed, and the motions are ripe for disposition.

The court views these motions as addressing case-management -- rather than substantive -- issues, and therefore deems it neither necessary nor productive to expend judicial resources producing a detailed written order. Rather, having fully and carefully considered the arguments presented by the parties, the court is persuaded on the facts of the instant case that in order to avoid jury confusion, the possibility of unfair prejudice to the parties' litigation rights, prejudice impacting from the resolution of state law claims upon the determination of patent issues, and to enhance the possibility of settlement, the following bifurcation is warranted:

It hereby is ORDERED that this litigation is BIFURCATED into two phases.

Phase I will resolve the issues of patent validity, enforceability, and infringement only.

---

<sup>2</sup> Barr's co-defendants Par Pharmaceutical, Inc., Dr. Reddy's Laboratories, Ltd., and Reddy-Cheminor, Inc. join in Barr's motion. See DE #66; DE #73.

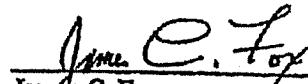
Phase II will resolve the willfulness of such infringement, if any, as has been determined in Phase I, as well as the damages, if any, arising therefrom. Phase II also will address all state law claims asserted by defendants (unfair trade practices, tortious contractual interference, and damages arising therefrom).

It further is ORDERED that discovery is STAYED *as to the issue of willful infringement only*; discovery relating to all other matters at issue shall proceed according to the rules and schedules applicable in this court and to this case. The Clerk of Court is DIRECTED to schedule and notice the trial of all Phase II issues approximately six months following the conclusion of Phase I.

Therefore, Barr's Motion to Bifurcate and to Stay Discovery (DE #54) is ALLOWED in part and DENIED in part, as set forth in detail herein. Similarly, aaIPHARMA's Motion to Bifurcate and to Stay Discovery (DE #63) is ALLOWED in part and DENIED in part, as set forth in detail herein.

SO ORDERED.

This the 9<sup>th</sup> day of September, 2002.

  
James C. Fox  
Senior United States District Judge

EX. 2

## Westlaw.

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 Slip Copy, 2005 WL 3971927 (D.Del.)  
 (Cite as: Slip Copy)

Page 1

**H**Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court, D. Delaware.  
 ALLERGAN, INC., and Allergan Sales, LLC,  
 Plaintiffs,  
 v.  
 ALCON INC., Alcon Laboratories, Inc., and Alcon  
 Research, Ltd., Defendants.  
 Civil Action No. 04-968 (GMS).

July 26, 2005.

William J. Marsden, Jr., Sean Paul Hayes, Fish & Richardson, P.C., Wilmington, DE, for Plaintiffs.  
Josy W. Ingersoll, Karen Elizabeth Keller, Young, Conaway, Stargatt & Taylor, Wilmington, DE, for Defendants.

**ORDER**

GREGORY M. SLEET, District Judge.

\*1 1. Allergan, Inc. and Allergan Sales, LLC (collectively, "Allergan") filed the above-captioned action against Alcon Inc., Alcon Laboratories, Inc., and Alcon Research, Ltd. (collectively, "Alcon") on August 24, 2004. Allergan filed this suit for patent infringement pursuant to 35 U.S.C. § 271(e)(2).<sup>FN1</sup> The complaint alleges that Alcon infringes U.S. Patent No. 6,673,337 (the "337 patent") and U.S. Patent No. 6,641,834 (the "834 patent") because it submitted a § 505(b)(2) application, or paper New Drug Application ("paper NDA"), to the Food and Drug Administration ("FDA"), seeking approval of its proposed generic brimonidine tartrate ophthalmic drug product.<sup>FN2</sup> (Compl. ¶¶ 14-15, 17.) The complaint further alleges that Alcon acted without a reasonable basis for believing that it would not be liable for infringement of the 337 and 834 patents and, as such, its infringement of the 337 and 834 patents is willful. (*Id.* ¶¶ 19, 23.) Allergan requests injunctive relief and attorney's fees, pursuant to 35 U.S.C. § 285.<sup>FN3</sup> The issue presently before the court is whether Allergan may assert a claim for willful infringement.

FN1. Section 271(e)(2) states, in pertinent part:

[i]t shall be an act of infringement to submit an application under section 505(j) of the

Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent. 35 U.S.C. § 271(e)(2)(A).

FN2. Alcon also filed a certification with the FDA under 21 C.F.R. § 314.50(i)(1)(i)(A)(4), or Paragraph IV Certification, alleging that the 337 and 834 patents are invalid and/or not infringed by its product.

FN3. Section 285 provides: "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." The Federal Circuit has recognized willful infringement as a type of misconduct that creates an exceptional case. *See Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1365 (Fed.Cir.2000) (citing *Beckman Instruments, Inc. v. LKB Produkter AB*, 894 F.2d 1547, 1151 (Fed.Cir.1989)).

2. Allergan contends that a willfulness claim is proper based on the totality of the circumstances. Allergan further contends that the totality of the circumstances comprises many factors, including whether Alcon intentionally copied ALPHAGAN® P, whether Alcon exercised due care to avoid infringing Allergan's patents, whether Alcon relied on competent legal advice, and Alcon's behavior as a party to the litigation. (D.I. 64, at 2.) According to Allergan, its claim of willfulness is based the following: (1) Alcon's Paragraph IV certification was filed without reasonable basis; and (2) Alcon's conduct in the litigation demonstrates its lack of reasonable basis. (*Id.* at 3). Lastly, Allergan contends that the Federal Circuit's holding in *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed.Cir.2004) does not foreclose a claim for willful infringement in Abbreviated New Drug Application ("ANDA") or paper NDA cases. (*Id.*)

3. Alcon asserts that the only act of infringement

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 (Cite as: Slip Copy)

Page 2

alleged in the complaint is the filing of its paper NDA with the FDA. According to Alcon, in light of the Federal Circuit's holding in *Glaxo*, "Allergan's conclusory allegation-standing alone-cannot support a charge of willful infringement." (D.I. 75, at 2.)

The Federal Circuit first addressed the issue of willfulness in ANDA and paper NDA cases in *Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339 (Fed. Cir.2000). In *Yamanouchi*, the court found that "[a]n ANDA [or paper NDA] filing by its very nature is a 'highly artificial act of infringement,' therefore, the trial court need not have elevated the ANDA certification into a finding of willful infringement." 231 F.3d at 1347. Nonetheless, the court held that the case was exceptional and awarded attorney fees to the plaintiff, based on the defendant's "misconduct in filing a wholly unjustified ANDA certification and misconduct during the litigation that followed..." *Id.*

\*2 The Federal Circuit addressed the issue again in *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed.Cir.2004), holding that "the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)." 376 F.3d at 1350-51. In the *Glaxo* opinion, the court explained that in *Yamanouchi* it "determined that a baseless and 'wholly unjustified' paragraph IV certification in an ANDA filing, when combined with litigation misconduct, warranted an exceptional case finding." *Id.* at 1350. According to the court, "in *Yamanouchi* we did not agree that the generic company had engaged in willful infringement, but rather determined that an award of attorney's fees was permitted because the generic had filed numerous baseless filings supporting its fruitless and meritless arguments, both in its case at trial and in its ANDA certification." *Id.*

6. In the present case, Allergan has not pointed to anything which would support a finding of willful infringement. The only act of infringement alleged in Allergan's complaint is Alcon's allegedly baseless paper NDA filing and Paragraph IV Certification with the FDA. Because a paper NDA filing cannot be considered willful, Allergan's complaint does not state any basis under which it could assert a claim for willful infringement. Allergan, however, maintains that Alcon's change in position with respect to its written description defense set forth in its summary judgment motion, combined with the paper NDA filing, permits a claim for willful infringement. The

court disagrees. As the Federal Circuit explained in *Glaxo*, a finding that a ANDA/paper NDA case is "exceptional" can be based on meritless filings combined with litigation misconduct, but a finding of willful infringement cannot. Accordingly, the court will not permit a claim for willful infringement in this case. That being said, the court will not foreclose Allergan from, at the appropriate time, seeking to prove additional facts that would support its claim of an exceptional case for which the court should award attorney's fees. See *Aventis Pharma Deutschland GmbH v. Cobalt Pharms., Inc.*, 355 F.Supp.2d 586, 592-93 (D.Mass.2005).

Therefore, IT IS HEREBY ORDERED that:

1. A claim for willful infringement is not permitted in this case.
2. Allergan's claim for willful infringement shall be stricken from the complaint.

D.Del.,2005.  
 Allergan, Inc. v. Alcon, Inc.  
 Slip Copy, 2005 WL 3971927 (D.Del.)

Briefs and Other Related Documents ([Back to top](#))

- [2006 WL 809119](#) (Trial Motion, Memorandum and Affidavit) Plaintiffs' Opposition to Defendants' Motion for Reargument or Reconsideration of its Motion for Leave to Amend its Answer (Feb. 15, 2006)
- [2005 WL 2603655](#) (Trial Motion, Memorandum and Affidavit) Plaintiffs' Reply Brief in Support of Plaintiffs' Provisional Motion to Amend the Scheduling Order (Sep. 2, 2005)
- [1:04cv00968](#) (Docket) (Aug. 24, 2004)

END OF DOCUMENT

EX. 3

## Westlaw.

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 Not Reported in F.Supp.2d, 2002 WL 1268047 (D.Del.)  
 (Cite as: Not Reported in F.Supp.2d)

Page 1

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Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court, D. Delaware.  
 ALLERGAN INC. and Allergan Sales, Inc.,  
 Plaintiffs,  
 v.  
 PHARMACIA CORPORATION, Pharmacia AB,  
 Pharmacia Enterprises S.A. and Pharmacia & Upjohn  
 Company, Defendants,  
 and THE TRUSTEES OF COLUMBIA  
 UNIVERSITY IN THE CITY OF NEW YORK,  
 Additional Defendant on Counterclaim in Reply.  
 No. Civ.A.01-141-SLR.

May 17, 2002.

## MEMORANDUM ORDER

ROBINSON, J.

\*I At Wilmington this 17th day of May, 2002, having reviewed the various pending discovery motions and the papers submitted in connection therewith;

IT IS ORDERED that:

1. Columbia's motion for a protective order precluding plaintiffs from deposing and obtaining documents from John P. White, Esquire (D.I. 77) is granted.

a. Plaintiffs have subpoenaed Columbia's lead trial counsel, Mr. White, to appear for a deposition on the issue of inventorship of U.S. Patent No. 4,599,353 ("the '353 patent"). More specifically, plaintiffs contend "that the inventor of the '353 patent, with Columbia's full knowledge and participation through its attorneys, failed to credit one or more co-inventors who collaborated in and contributed to the conception and reduction to practice of the '353 invention." (D.I. 87 at 4) Plaintiffs argue that Mr. White has relevant information based on an amendment filed by Mr. White wherein he declares that "[a]pplicant is the sole inventor of the invention described and claimed in the subject application." (*Id.*, Ex. 2 at 4) The amendment reflects facts as averred by the inventor in his declaration. (*Id.*, Ex. 3)

b. As a general principle, depositions of trial counsel

are limited to those circumstances where "the party seeking to take the deposition has shown that (1) no other means exist to obtain the information than to depose opposing counsel; (2) the information sought is relevant and nonprivileged; and (3) the information is crucial to the preparation of the case." *Shelton v. Am. Motors Corp.*, 805 F.2d 1323, 1327 (8th Cir.1987) (internal citation omitted). Cf., *Environ Prods., Inc. v. Total Containment, Inc.*, 41 U.S.P.Q.2d 1302, 1306 (E.D.Pa.1996) ("Impressions protected by the work-product doctrine may be discovered when directly relevant to the litigation and when the need for production is compelling."); *Bio-Rad Labs., Inc. v. Pharmacia, Inc.*, 130 F. R.D. 116, 122 (N.D.Cal.1990) ("[A]n attorney's opinion work product is discoverable where such information is directly at issue and the need for production is compelling."). Moreover, absent a *prima facie* showing of fraud, an allegation of inequitable conduct, in and of itself, does not vitiate the attorney-client privilege or the protections of the attorney work product doctrine. See *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 806-07 (Fed.Cir.2000).

c. The court concludes that plaintiffs have not met their burden to demonstrate a compelling need for the requested discovery. Plaintiffs apparently contend, in support of their inequitable conduct contentions, that Mr. White knew or should have known that one or more co-inventors collaborated in and contributed to the conception and reduction to practice of the patented invention and was obligated to so inform the PTO. The court suggests that until such time as plaintiffs have demonstrated the truth of the matters asserted (i.e., there were co-inventors), Mr. White's knowledge is irrelevant. Because the issue of inequitable conduct is a matter for the court to determine, and because the factual predicate to the issue of inventorship can be pursued independent of Mr. White's testimony (through the depositions of the inventor and alleged co-inventors and through access to the documents that reflect the inventive process), the court declines to permit the deposition of Mr. White at this time.

\*2 2. Defendants' motion to compel the production of documents (D.I.82) is granted to the extent explained below.

a. Defendants have moved to compel plaintiffs to

Not Reported in F.Supp.2d  
 Not Reported in F.Supp.2d, 2002 WL 1268047 (D.Del.)  
 (Cite as: Not Reported in F.Supp.2d)

Page 2

produce "all documents relating to the subject matter of three opinion letters provided by their counsel, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP ("Finnegan, Henderson"), and to permit questioning of Allergan witnesses regarding the subject matter of those opinion letters." (*Id.* at 1) By way of background, plaintiffs have chosen to rely upon the opinions written by Finnegan, Henderson in defense of the claim of willful infringement. Plaintiffs have produced the three opinion letters and drafts thereof, and "all communications between Allergan and Finnegan regarding those letters as well as all of the materials that Allergan considered in connection with its reliance on the letters." Defendants seek, in addition to the above, "documents relating to [Allergan's] other infringement and validity analyses of the patents." (*Id.* at 3)

b. From the court's perspective, the question posed by this discovery dispute is whether the scope of a party's voluntary waiver is defined by the course of conduct between the party and its opinion counsel, or whether it is defined by the subject matter discussed in the opinion letters. The court concludes that it is the latter.

c. It is undisputed that, [w]hen an alleged infringer decides to respond to a claim of willful infringement by offering evidence that he or she reasonably and in good faith relied on advice of counsel in making, using or selling the allegedly infringing device, then the advice becomes relevant and admissible. Documents and testimony relating to that advice are relevant in that they are probative of the alleged infringer's intent. They are admissible because the alleged infringer has waived the privilege as to the subject matter of the advice.

Thorn EMI North Am., Inc. v. Micron Tech., Inc., 837 F.Supp. 616, 621 (D.Del.1993). In order to determine whether the alleged willful infringer "reasonably and in good faith relied on" the advice rendered by opinion counsel, it is appropriate to test the knowledge of the alleged willful infringer concerning the subject matter of the opinion. *Cf. id.* (the patentee should be entitled to discover facts relating to what the alleged willful infringer "knew and had concluded about the credibility, value and reasonableness of the opinions.").

d. Consistent with the above reasoning, the court concludes that the only equitable way for a patentee to test the knowledge of an alleged willful infringer (so as to test the reasonableness of its evaluation of

counsel's opinions) is for the alleged willful infringer to disclose all of the information it possessed prior to or at the time it obtained opinions of counsel as to the subject matters discussed in such opinions.<sup>FN1</sup>

FN1. The court recognizes that the scope of discovery allowed at bar is relatively broad and potentially prejudicial to plaintiffs. Therefore, rather than requiring disclosure consistent with this order at this time, the court will bifurcate the issue of willfulness, stay discovery relating to willfulness, and conduct a separate trial with a new jury in the event plaintiffs are found to infringe valid patents. *See Novartis Pharms. Corp. v. Eon Labs Mfg., Inc.*, No. 00-800-JJF, 2002 WL 576088, at \*3 n. 2 (D.Del. Mar. 28, 2002).

3. Plaintiffs' motion to compel the production of documents withheld under the common legal interest doctrine (D.I.99) is denied as untimely. The parties agreed to exchange their privilege logs on January 23, 2002. By stipulation filed on March 11, 2002, the discovery cutoff date was extended to March 15, 2002. Plaintiffs filed the instant motion on April 8, 2002. Motions that relate to fact discovery must be filed during fact discovery, especially where, as here, the underlying facts relating to the motion were known to plaintiffs in January 2002. Therefore, the court declines to address the motion on its merits.

\*3 4. Plaintiffs' motion for leave to file a sur-reply brief (D.I.96) is denied as moot.

D.Del.,2002.  
 Allergan Inc. v. Pharmacia Corp.  
 Not Reported in F.Supp.2d, 2002 WL 1268047 (D.Del.)

Briefs and Other Related Documents ([Back to top](#))

• [1:01CV00141](#) (Docket) (Mar. 01, 2001)

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EX. 4

## Westlaw.

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 Not Reported in F.Supp.2d, 2003 WL 21557632 (N.D.Ill.)  
 (Cite as: Not Reported in F.Supp.2d)

Page 1

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Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court, N.D. Illinois, Eastern  
 Division.

APTARGROUP, INC., Plaintiff,  
 v.

OWENS-ILLINOIS, INC. and Armin Tool and  
 Manufacturing Co., Defendants.

No. 02 C 5058.

July 3, 2003.

MEMORANDUM OPINION AND ORDER

MORAN, Senior J.

\*1 Defendants move to bifurcate the issues of liability and willfulness for purposes of discovery and trial. That motion is granted.

The parties agree on one thing: bifurcation is within the sound discretion of the court. Each marshalls a number of cases in support of its opposing position, with defendants seeking bifurcation and plaintiff opposing it. A review of those cases discloses such varied circumstances that an extended analysis of each case serves little purpose. A few observations will suffice. The Federal Circuit encourages bifurcation when a party is faced with what has come to be known as the "Quantum dilemma": a choice between the lawful assertion of the attorney-client privilege and avoidance of a willfulness finding if infringement is found. *Quantum Corp. v. Tandon Corp.*, 940 F.2d 642 (Fed.Cir.1991). The support from some of the professional literature is even stronger. The district courts are reluctant to bifurcate, however, if there is not a good reason to bifurcate damages as well, or it is uncertain that the party faces the "Quantum dilemma," or legal advice becomes relevant for other reasons, or prior rulings establish that the patent holder has a strong liability case (although this last reason appears to be somewhat of a make-weight). They divide as to whether or not intent can ever be relevant to a non-infringement defense.

Here the "Quantum dilemma" is raised by the submission of attorney opinion letters *in camera*. The issue of damages has already been bifurcated, there appears to be no reason why legal advice would be

relevant to any issue other than willfulness, and plaintiff's liability case has taken a real hit from this court's *Markman* construction. Finally, we think there is a basis for believing that an "intent" issue mixed up with an infringement issue will have a tendency to confuse and possibly prejudice the jury, without any real relevant evidence benefit.

N.D.Ill.,2003.

Aptargroup, Inc. v. Owens-Illinois, Inc.

Not Reported in F.Supp.2d, 2003 WL 21557632 (N.D.Ill.)

Briefs and Other Related Documents (Back to top)

- [2003 WL 23419339](#) (Trial Motion, Memorandum and Affidavit) Agreed Motion for Disposition of Restricted Documents (Oct. 06, 2003)
- [2003 WL 23419335](#) (Trial Motion, Memorandum and Affidavit) Plaintiff Aptargroup's Motion to Set A Scheduling Order (Jul. 08, 2003)
- [2003 WL 23419336](#) (Trial Motion, Memorandum and Affidavit) Plaintiff Aptargroup's Motion to Strike Defendants' Affirmative Defenses (Jul. 08, 2003)
- [2003 WL 23419333](#) (Trial Motion, Memorandum and Affidavit) Defendants' Memorandum in Support of Motion to Bifurcate Issues of Liability and Willfulness (Jun. 04, 2003)
- [2003 WL 23419334](#) (Trial Motion, Memorandum and Affidavit) Plaintiff Aptargroup's Brief Opposing Bifurcation of Willfulness from Liability (Jun. 04, 2003)
- [2003 WL 23816942](#) (Trial Motion, Memorandum and Affidavit) Defendants' Memorandum in Support of Motion to Bifurcate Issues of Liability and Willfulness (Jun. 4, 2003)
- [2003 WL 23816944](#) (Trial Motion, Memorandum and Affidavit) Plaintiff Aptargroup's Brief Opposing Bifurcation of Willfulness From Liability (Jun. 4, 2003)
- [2003 WL 23816940](#) (Trial Motion, Memorandum and Affidavit) Plaintiff's Reply in Support of Its Motion to Compel Disclosure of Valve Measurement Data (May 19, 2003)
- [2003 WL 23419330](#) (Trial Motion, Memorandum and Affidavit) Agreed Motion and Proposed Order Moving by One Day the Time to File Status Reports, and to Reschedule the Status Hearing (May. 02, 2003)
- [2003 WL 23419323](#) (Trial Motion, Memorandum and Affidavit) Plaintiff Aptargroup's Reply Brief on

Not Reported in F.Supp.2d  
Not Reported in F.Supp.2d, 2003 WL 21557632 (N.D.Ill.)  
(Cite as: Not Reported in F.Supp.2d)

Page 2

Claim Construction (Feb. 25, 2003)

- 2003 WL 23419327 (Trial Motion, Memorandum and Affidavit) Defendants' Response Brief Regarding Claim Construction (Feb. 25, 2003)
- 2003 WL 23816934 (Trial Motion, Memorandum and Affidavit) Plaintiff Aptargroup's Reply Brief on Claim Construction (Feb. 25, 2003)
- 2003 WL 23816935 (Trial Motion, Memorandum and Affidavit) Defendants' Response Brief Regarding Claim Construction (Feb. 25, 2003)
- 2003 WL 23419318 (Trial Motion, Memorandum and Affidavit) Defendants' Initial Brief Regarding Claim Construction (Feb. 04, 2003)
- 2003 WL 23419320 (Trial Motion, Memorandum and Affidavit) Plaintiff Aptargroup's Opening Brief on Claim Construction (Feb. 04, 2003)
- 2002 WL 32674603 (Trial Motion, Memorandum and Affidavit) Plaintiff Aptargroup's Response to Defendants' Status Report (Dec. 2, 2002)
- 2002 WL 32452958 (Trial Motion, Memorandum and Affidavit) Plaintiffs Motion to Compel Production of 30(b)(6) Witnesses (Oct. 25, 2002)
- 2002 WL 32674594 (Trial Pleading) Armin Tool and Manufacturing Co.'s Answer and Affirmative Defenses (Aug. 27, 2002)
- 2002 WL 32674587 (Trial Pleading) Owens-Illinois, Inc.'s Answer and Affirmative Defenses (Aug. 21, 2002)
- 2002 WL 32674578 (Trial Pleading) Complaint for Patent Infringement (Jul. 17, 2002)
- 1:02CV05058 (Docket) (Jul. 17, 2002)

END OF DOCUMENT

EX. 5

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

206

ARTHROCARE CORPORATION, )  
 )  
Plaintiff, )  
 )  
v. ) C.A. No. 01-504-SLR  
 )  
SMITH & NEPHEW, INC., )  
 )  
Defendant. )

MEMORANDUM ORDER

At Wilmington this 27th day of November, 2002; having reviewed the papers submitted by the parties in connection with various motions filed by defendant;

IT IS ORDERED that defendant's motion to stay pending reexamination (D.I. 187) is denied, for the reasons that follow:

1. The United States Court of Appeals for the Federal Circuit recognizes that "[c]ourts have inherent power to manage their dockets and stay proceedings . . . , including the authority to order a stay pending conclusion of a PTO reexamination." Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1426-27 (Fed. Cir. 1988) (citations omitted). Courts clearly have the authority to order their cases to trial.

2. The Federal Circuit also has recognized that patent litigation in a district court and reexamination proceedings

before the PTO do not implicate a "precise duplication of effort" because "litigation and reexamination are distinct proceedings, with distinct parties, purposes, procedures, and outcomes." Id. at 1427.

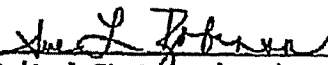
3. Given the court's view that its primary purpose is to manage litigation in an expeditious manner in order to create an appropriate record (through motion practice or trial) for review by the Federal Circuit, the court generally will not stay its cases pending reexamination proceedings absent extraordinary circumstances. In this case, where only one of the three patents is undergoing reexamination, where the patents at issue relate to an evolving and highly competitive market, and where the reexamination proceedings to date have not been conducted with what the court would consider "special dispatch", the court declines to find this an exceptional case warranting a stay. The court understands that, prior to trial, the PTO may issue rulings that will need to be considered, thus causing some inefficiencies in the pretrial and trial process. Nevertheless, the court concludes that such inefficiencies are an inherent byproduct of concurrent litigation and reexamination and, therefore, do not constitute exceptional circumstances justifying a stay of the litigation at bar.

IT IS FURTHER ORDERED that defendant's motion to bifurcate willfulness and damages and to stay discovery (D.I. 107) is granted. Discovery on the issues of willfulness and damages will be stayed until after the verdict on infringement and invalidity has been returned; these issues will be tried to a new jury.

IT IS FURTHER ORDERED that defendant's claim of privilege pertaining to redactions in certain documents (D.I. 190) is denied. The court finds that the information redacted is equivalent to the information required to be included in a privilege log, and thus not privileged information.

IT IS FURTHER ORDERED that defendant's second motion for leave to amend answer and counterclaim (D.I. 111) is granted. However, discovery and trial of defendant's newly added counterclaim for antitrust violations are stayed consistent with the above ruling on the issues of damages and willfulness.

IT IS FURTHER ORDERED that defendant's motion for reargument is denied, as is its motion to strike. (D.I. 160, 172)

  
United States District Judge

EX. 6

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF INDIANA  
INDIANAPOLIS DIVISION

ENTERED

APR 01 2004

U.S. CLERK'S OFFICE  
INDIANAPOLIS, INDIANA

ELI LILLY AND COMPANY,

Plaintiff,

v.

BARR LABORATORIES, INC.,

Defendant.

)  
) Civil Action No. 1:02-CV-1844-SEB  
)  
) Judge Sarah Evans Barker  
)  
) Magistrate Judge V. Sue Shields  
)  
)  
)  
)

ENTRY

THIS CAUSE COMES before the Court on Defendant Barr Laboratories, Inc.'s Motion to Bifurcate and Stay Discovery on Plaintiff Eli Lilly and Company's Willful Infringement Claims. Having reviewed Defendants' motion and the related pleadings,

IT IS HEREBY ORDERED that Barr's motion to bifurcate Lilly's willfulness claims is GRANTED and all discovery on Lilly's willful infringement claims is STAYED until resolution of all liability issues.

Dated: March 31, 2003

Sarah Evans Barker  
Hon. Sarah Evans Barker  
United States District Judge  
United States District Court for the  
Southern District of Indiana

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EX. 7

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF INDIANA  
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,

Plaintiff,

vs.

IP 96-0419-C-B/S

BARR LABORATORIES, INC.,  
APOTEX, INC., INTERPHARM, INC.,  
BERNARD C. SHERMAN and GENEVA  
PHARMACEUTICALS, INC.,

Defendants.

ENTRY

This matter comes before the Court on (1) a motion by Plaintiff Eli Lilly and Company ("Lilly") to amend the complaint to add a claim for willful infringement, (2) a motion by Defendant Barr Laboratories, Inc ("Barr") for bifurcation of the issues of liability and the willful infringement claim under Federal Rule of Civil Procedure 42(b) and a stay of discovery on the willful infringement claim<sup>1</sup> and (3) Lilly's motion to deem admitted a fact establishing infringement by Geneva. This case involves complex issues of intellectual property law and scientific and technological evidence and is set for trial in January 1999, a mere three months away. Barr's primary objection to Lilly's motion to amend the complaint is for reasons of undue prejudice, as addressed more fully in Barr's

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<sup>1</sup>We note that Defendant Geneva Pharmaceuticals, Inc. ("Geneva") joins in Barr's motion to bifurcate in its objection to Lilly's motion to amend.

motion to bifurcate the issues of liability and willful infringement. Thus, we find it most efficient to address Barr's motion to bifurcate first.

Rule 42(b) provides, "The court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy, may order a separate trial of any claim . . . or of any separate issue . . . , always preserving inviolate the right of trial by jury . . . ." Barr moves for bifurcation, arguing that Lilly's raising this new claim so late in the litigation of the case will prejudice Barr, that there is not sufficient time to prepare the willful infringement claim and defenses for the scheduled January 1999 trial date, that presentation of evidence regarding willful infringement will confuse the trier of fact unnecessarily and that Lilly will not be prejudiced by separate trials and a stay of discovery. Lilly asserts that bifurcation will result in "an immense waste of resources and duplication of effort" and evidence. See Plaint. Opp. Bifurc. at 1.

Having considered the parties' arguments on this issue in their briefs and the facts in this case, we conclude that the newly-raised claim of willful infringement should be tried separately from the issue of liability and that discovery on the willful infringement claim should be stayed until the liability phase of this case is complete (1) to avoid undue prejudice to Barr, (2) to prevent forcing Barr to choose between the advice of counsel defense to willful infringement and asserting attorney-client privilege, as would be implicated in this case, and (3) in the interests of judicial economy and efficiency. See,

e.g., Quantum Corp. v. Tandon Corp., 940 F.2d 642, 644 (Fed. Cir. 1991); Princeton Biochemicals, Inc. v. Beckman Instrumentals, Inc., 45 U.S.P.Q.2d 1757, 1761 (D.N.J. 1997); In re Recombinant DNA Technology Patent and Contract Litigation, 30 U.S.P.Q.2d 1881, 1900 (S.D. Ind. 1994). Accordingly, we grant Barr's motion to bifurcate liability and willful infringement and stay discovery on the willful infringement claim until liability for infringement has been determined.

Having disposed of Barr's concerns regarding prejudice, we now turn to Lilly's motion to amend the complaint. Geneva and Barr both object to Lilly's motion, contending that Lilly fails to state a claim of willful infringement, arguing that the filing of an Abbreviated New Drug Application ("ANDA") cannot give rise to an allegation of willful infringement. After considering the parties' arguments and supporting authority, we conclude that it is by no means clear that Lilly's willful infringement claim is futile and that further factual development is necessary to determine the merits of Lilly's claim. See, e.g., Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc., 1998 WL 696011 (S.D.N.Y. Oct. 1, 1998). Thus, we grant Lilly's motion to amend the complaint. However, Defendants may want to reassert their objections later in the event that the willful infringement claim remains viable after liability has been determined.

Lilly also seeks an order deeming admitted a fact establishing Geneva's infringement of claim 7 of Lilly's '549 patent. Lilly claims that Geneva's response to Lilly's third set of interrogatories constitutes an admission of infringement. This issue is

somewhat complicated because it does not appear that Geneva disputes infringement, precisely, but only challenges the use of its response to Lilly's interrogatories. It seems as though if Lilly simply had asked Geneva in its interrogatories to admit infringement of claim 7 of the '549 patent in the same language Lilly uses with respect to claim 5 of the '081 patent, Lilly may have received the admission it sought. Rather, Lilly appears to have been fishing for some broader type of admission relevant to other of its claims or defenses, which strategy Geneva resisted. Geneva's response may well constitute an admission of infringement of claim 7, but we find that this is an evidentiary dispute more properly resolved at trial. Lilly should proffer the evidence at trial, proposing it as an admission by Geneva, and it will be for the trier of fact, whether it be a jury or this Court, to conclude whether Geneva's response constitutes an admission of infringement. Accordingly, we deny Lilly's motion at this time. However, we encourage Lilly and Geneva to attempt to reach a stipulation before trial as to any issues that are not genuinely in dispute, such as whether Geneva admits infringement of claim 7, to save the Court from trying the issue of infringement unnecessarily.

Lilly also requests temporary ancillary relief from filing an expert report on infringement issues. Such report was due on August 14, 1998, which date was extended by the Court to August 21, 1998, and Lilly requested additional time to file its report until after the Court disposed of the motion to deem admitted the fact establishing infringement by Geneva. If Lilly has not already submitted its expert report on this issue, it should do

so no later than November 20, 1998, three weeks from the date of this entry, if it finds such report necessary after the Court's ruling and after attempting to enter into a stipulation with Geneva.

For the reasons set forth above, we grant Lilly's motion to amend, grant Barr's motion for bifurcation and stay of discovery and deny Lilly's motion to deem admitted Geneva's infringement.

It is so ORDERED this 29<sup>th</sup> day of October 1998.

Sarah Evans Barker  
SARAH EVANS BARKER, CHIEF JUDGE  
United States District Court  
Southern District of Indiana

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EX. 8

IN THE UNITED STATES DISTRICT COURT  
IN AND FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT :  
INFRINGEMENT LITIGATION, : CIVIL ACTION  
: NO. 05-356 (KAJ)  
: (Consolidated)

Wilmington, Delaware  
Friday, March 3, 2006 at 9:30 o'clock, a.m.  
TUTORIAL CONFERENCE

BEFORE: HONORABLE KENT A. JORDAN, U.S.D.C.J.

APPEARANCES:

ASHBY & GEDDES  
BY: STEVEN J. BALICK, ESQ.

-and-

COVINGTON & BURLING  
BY: GEORGE F. PAPPAS, ESQ.,  
CHRISTOPHER N. SIPES, ESQ., and  
JOSEPH H. HUYNH, ESQ.  
(Washington, District of Columbia)

-and-

JOHNSON & JOHNSON  
OFFICE OF THE GENERAL COUNSEL  
BY: STEVEN P. BERMAN, ESQ.  
(New Brunswick, New Jersey)

Counsel for Janssen Pharmaceutica  
N.V., Janssen, L.P. and Synaptech Inc.

Brian P. Gaffigan  
Registered Merit Reporter

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P R O C E E D I N G S

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(REPORTER'S NOTE: The following tutorial  
conference was held in open court, beginning at 9:30 a.m.)

6

THE COURT: Good morning. Please be seated.

7

We have a couple things to deal with today.

8

This has been on the calendar for some time for a tutorial.

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I appreciate everybody being here.

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Before we get the cameras rolling on us for the  
tutorial, I did want to -- and I gave a heads up to you kind  
of late in the day but I gave a head's up yesterday that I  
was wanting to talk to you about the motions to strike the  
willfulness or the motion to dismiss the willfulness claim.  
And I am going to go ahead and nobody has to say anything  
more than they have said in the papers if they don't want to  
but if there is something you want to add to the papers,  
this is a pretty straightforward issue, I'll hear you on it.

Ms. Matterer, is there anything from your side?  
I believe it's Mylan's motion.

MS. MATTERER: That's correct, Your Honor. This  
is William Rakoczy from Rakoczy Molino Mazzochi Siwik.

MR. RAKOCZY: Good morning, judge.

THE COURT: Good morning.

MR. RAKOCZY: Should I approach the podium?

1 THE COURT: Sure, that's fine. Please.

2 MR. RAKOCZY: William Rakoczy for the Mylan  
3 defendants on the motion in which all the defendants have  
4 joined. We would just add, we just want to confirm the  
5 Court in fact got the last citation we submitted.

6 THE COURT: I did. I got that Northern District  
7 of Georgia case a couple days ago.

8 MR. RAKOCZY: Unless Your Honor has any  
9 questions for us, we have nothing outside what is in our  
10 papers.

11 THE COURT: I don't.

12 Mr. Pappas.

13 MR. RAKOCZY: Thank you, Judge.

14 MR. PAPPAS: Good morning, Your Honor. George  
15 Pappas on behalf of the plaintiffs.

16 I would just say in slight addition to our  
17 papers that having reviewed the authorities that have been  
18 cited by the defendants, it's clear to us that this is an  
19 issue on which District Courts throughout the country  
20 disagree. The Federal Circuit has not clearly spoken to it  
21 and we believe that the willfulness claim should proceed and  
22 particularly on our particular facts, we have to develop a  
23 full record.

24 THE COURT: Okay. Thanks. Well, there is going  
25 to be plenty on this case for me to be writing memoranda

1 orders and opinions and holding forth at length on various  
2 aspects of patent law. I don't think I need to add to the  
3 written opinions that already exist on this. I'm granting  
4 the motion.

5 Judge Sleet has already spoken on this subject  
6 in this District. I think the Glaxo case is clearer than  
7 some people might think it is. When they say mere fact that  
8 a company has filed an ANDA application or certification  
9 cannot support a finding of willfulness, I don't think that  
10 leaves the door open the way the plaintiffs seem to say,  
11 well, this isn't a mere filing, it's a baseless filing and,  
12 therefore, it's somehow more problematic than that.

13 And that argument was specifically addressed the  
14 in the Lupin case, which was an Eastern District of Virginia  
15 case that came out just last month, January of this year.  
16 And I don't think I can say it better than this. That Court  
17 noted that -- headnote one, it's page seven of the slip  
18 opinion -- that even a baseless ANDA filing could not  
19 constitute an act of willful infringement, although a  
20 baseless ANDA filing could constitute an exceptional case.  
21 I think that Court has it right.

22 I'm saying nothing about whether or not there  
23 may be some litigation, misconduct or purpose or a found-  
24 ation for sanction at some point. I'm just not getting into  
25 that. I'm making a statement solely on the issue of whether

1 there is a claim for willfulness; and I think the courts,  
2 the authority is steadily building against the plaintiffs'  
3 position. I accept the authority that says they don't have  
4 a claim in this case for willfulness.

5 So I'll issue an order that says for the reasons  
6 stated in open court, the motion to dismiss willfulness  
7 claim is granted. And, again, I reiterate I'm basing this  
8 and adopting the logic set forth in Lupin and Judge Sleet's  
9 opinion, the Allergan vs. Alcon case as well as the more  
10 recent, I guess it's a February 28th decision coming out of  
11 the Northern District of California that was submitted.

12 Okay. Since we were all together, I thought it  
13 would be productive to get that taken of. That way we know  
14 what we're dealing with going forward.

15 This is also now my opportunity to have you  
16 folks take me to school and I appreciate your all being here  
17 and prepared and ready to do that for me. And why don't I  
18 give the podium first to Mr. Pappas to speak on behalf of  
19 the plaintiffs.

20 MR. PAPPAS: Your Honor, again George Pappas on  
21 behalf of the plaintiffs.

22 Your Honor, this is our chance to give you the  
23 tutorial on the basic fundamental technology we think will  
24 assist you in this case. We have chosen to proceed  
25 electronically today. We had advised the other side we

EX. 9

## Westlaw.

Not Reported in F.Supp.2d  
 Not Reported in F.Supp.2d, 2004 WL 2758672 (D.Del.)  
 (Cite as: Not Reported in F.Supp.2d)

Page 1

**H**Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court, D. Delaware.  
 INTEGRAL RESOURCES (PVT) LIMITED, a  
 Pakistani corporation, Plaintiff,  
 v.  
 ISTIL GROUP, INC., a Delaware corporation,  
 Defendant.  
 No. 03-904 (GMS).

Dec. 2, 2004.

Joseph S. Naylor, Pepper Hamilton LLP,  
 Wilmington, DE, for Plaintiff.  
 Norman M. Monhait, Rosenthal, Monhait, Gross &  
 Goddess, Wilmington, DE, for Defendant.

## MEMORANDUM

SLEET, J.

## I. INTRODUCTION

\*1 The plaintiff, Integral Resources (PVT) Limited ("Integral"), filed the above-captioned action against ISTIL Group, Inc. ("ISTIL") on September 24, 2003. In its complaint, Integral alleges that ISTIL interfered with its contractual relationship with the Progress Agency ("Progress"), a Ukrainian Republic foreign trade firm and agency of the government of Ukraine, by inducing Progress to terminate its contract with Integral. Integral further alleges that ISTIL interfered with prospective contractual relations arising from Integral's long-term business relationship with Progress.

Presently before the court is ISTIL's renewed motion to dismiss Integral's complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. For the reasons that follow, the court will grant ISTIL's motion.

## II. BACKGROUND

Integral, a military equipment consultant, is incorporated under the laws of Pakistan, with its principal place of business in Pakistan. ISTIL is a Delaware corporation, with its principal place of

business in West Linn, Oregon. <sup>FN1</sup> ISTIL is engaged in the business of manufacturing and trading steel products.

<sup>FN1</sup> ISTIL disputes this allegation, asserting that it is not registered to do business in Oregon and that its principle place of business is Ukraine. However, he court must accept as true the well-pleaded allegations of the complaint. See Doug Grant Inc. v. Great Bay Casino Corp., 232 F.3d 173, 183-84 (3d Cir.2000). Thus, the court will consider Oregon as ISTIL's principle place of business for purposes of this motion.

Integral alleges that, on November 4, 1995, it entered into a contract with Progress (the "Progress Contract") to assist Progress in developing, marketing, and implementing the sale of military equipment-initially the T-80 UD tank-for the government of Pakistan. The Progress Contract was allegedly amended several times after its execution, enlarging the scope of Integral's business relationship with Progress. Specifically, Integral was to be the sole and exclusive commercial consultant on all projects between Progress and the Pakistani government, including, but not limited to, the A1-Kahlid tank project. Additionally, Integral and Progress agreed by amendment that the contract between them would remain in effect as long as the T-80 UD tank remained in service for the Pakistani government.

Integral further alleges that, in 2001, ISTIL embarked on a mission to usurp the economic benefits of the Progress Contract and to disrupt Integral's business relationship with Progress. According to Integral, ISTIL, with the aid of its Ukrainian lawyers, specifically Volodymyr Petryna ("Petryna"), formed Reventox Consulting Limited ("Reventox"), a company incorporated under the laws of Cyprus. ISTIL then had Petryna approach and falsely advise Progress that it would be permissible to breach the Progress Contract in order to enter into a new agreement with Reventox.

According to the complaint, at the time that ISTIL and Petryna induced Progress to terminate the Progress Contract, they knew that the termination

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 Not Reported in F.Supp.2d, 2004 WL 2758672 (D.Del.)  
 (Cite as: Not Reported in F.Supp.2d)

Page 2

would violate the terms of the contract, and that their efforts to interfere with the contract were unlawful. Petryna allegedly advised ISTIL that there was a need for secrecy and that it should devise a plan to avoid suspicions concerning its actions.

As a result of ISTIL's and Petryna's efforts, Progress allegedly terminated the Progress Contract, entered into a new contract with Reventox (the "Reventox Contract"), and severed its long-standing business relationship with Integral.

\*2 Integral additionally alleges that the Reventox Contract was a fraud at its inception because it violated a contract between the Pakistani and Ukrainian governments. According to Integral, the terms of the Reventox Contract authorized the payment of millions of dollars of commissions to Reventox for Progress. ISTIL then used these "secret commissions" to pay kickbacks to, among others, the representatives of Progress who allegedly participated in and authorized ISTIL's efforts to steal the Progress Contract.<sup>FN2</sup>

FN2. ISTIL's alleged criminal conduct is not at issue in the present case. Thus, the court will not address Integral's allegations of fraud with respect to the Reventox Contract.

On September 24, 2003, Integral filed its complaint, alleging tortious interference with a contract and tortious interference with prospective contractual relations. On November 10, 2003, ISTIL filed a motion to dismiss under the doctrine of *forum non conveniens*, arguing that the case should be heard in Ukraine, not in Delaware. Alternatively, ISTIL moved for dismissal pursuant to Federal Rule of Civil Procedure 12(b)(6), contending that Integral had failed to state a claim for which relief could be granted under Ukrainian law.

On January 5, 2004, the court issued an order denying ISTIL's motion to dismiss, without prejudice, on the ground of *forum non conveniens*. The court declined to issue a ruling on ISTIL's Rule 12(b)(6) motion because the factual record on the choice-of-law issue was not yet fully developed. The court subsequently ordered the parties to conduct limited discovery and requested further briefing on the choice-of-law issue. On April 2, 2004, ISTIL filed a renewed Rule 12(b)(6) motion to dismiss.

### III. STANDARD OF REVIEW

ISTIL moves to dismiss the complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). Dismissal is appropriate pursuant to this Rule if the complaint fails "to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). In this inquiry, the court must accept as true and view in the light most favorable to the non-movant the well-pleaded allegations of the complaint. Doug Grant, Inc. v. Great Bay Casino Corp., 232 F.3d 173, 183-84 (3d Cir.2000). The court "need not accept as true 'unsupported conclusions and unwarranted inferences.'" *Id.* (quoting City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 263 n. 13 (3d Cir.1998)) (quoting Schuylkill Energy Res., Inc. v. Pennsylvania Power & Light Co., 113 F.3d 405, 417 (3d Cir.1997)). However, it is the duty of the court "to view the complaint as a whole and to base rulings not upon the presence of mere words but, rather, upon the presence of a factual situation which is or is not justiciable." *Id.* at 184 (quoting City of Pittsburgh, 147 F.3d at 263).

### IV. DISCUSSION

#### A. Choice of Law

Before the court addresses the sufficiency of Integral's complaint, it must determine whether Delaware or Ukrainian law applies to Integral's allegations.<sup>FN3</sup> Delaware courts apply the "most significant relationship test" of the Second Restatement of Conflicts. See Travelers Indemnity Co. v. Lake, 594 A.2d 38, 47 (Del.1991) (adopting the most significant relationship test from the Second Restatement of Conflicts). Section 145 of the Restatement directs the court to apply the law of the state that "has the most significant relationship to the occurrence and the parties under the principles stated in § 6." Restatement (Second) of Conflict of Laws § 145. After applying the factors set forth in Sections 145 and 6 and evaluating the contacts according to their relative importance with respect to the alleged tortious acts, the court concludes that Ukraine, not Delaware, has the most significant relationship to the acts. Thus, Ukrainian law applies to the claims asserted by Integral.<sup>FN4</sup>

FN3. The court will apply Delaware choice of law rules to determine what law governs Integral's claims. See, e.g., Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 61

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 Not Reported in F.Supp.2d, 2004 WL 2758672 (D.Del.)  
 (Cite as: Not Reported in F.Supp.2d)

Page 3

S.Ct. 1020, 85 L.Ed. 1477 (1941); *Brown v. SAP America, Inc.*, No. C.A. 98-507-SLR, 1999 WL 803888, at \*4 (D.Del. Sept.13, 1999).

FN4. Indeed, the only reference to Delaware in the complaint is in paragraph two, which alleges that ISTIL is a corporation organized and existing under the laws of Delaware.

#### 1. Section 145 Factors

\*3 Section 145 sets forth the relevant contacts that the court should consider when applying the principles of § 6 to determine the law applicable to an issue. These factors include: (1) the place where the injury occurred; (2) the place where the conduct causing the injury occurred; (3) the domicile, residence, nationality, place of incorporation and place of business of the parties; and (4) the place where the relationship, if any, between the parties is centered. *Id.* The court should evaluate the contacts according to their relative importance with respect to the particular issue. *Id.*; see also *Travelers Indemnity*, 594 A.2d at 48 (“[T]he Restatement test does not authorize a court to simply add up the interests on both sides of the equation and automatically apply the law of the jurisdiction meeting the highest number of contacts listed in sections 145 and 6. Section 145 has a qualitative aspect.”).

The complaint alleges that ISTIL, with the aid of its Ukrainian lawyers, more specifically Petryna, orchestrated a scheme to usurp from Integral the economic benefits of the Progress Contract and its business relationship with Progress. The Progress Contract that is the subject of ISTIL's alleged unlawful conduct was negotiated and performed in Ukraine and Pakistan. The places of injury are, therefore, Ukraine and Pakistan.<sup>FN5</sup>

FN5. Neither party has argued that the court should apply Pakistani law.

The place where the conduct causing the injury occurred is Ukraine. Integral alleges that ISTIL and Petryna induced Progress to breach the Progress Contract. ISTIL's wrongful conduct includes placing Petryna at Progress' disposal in Ukraine. As previously discussed, Petryna then allegedly advised Progress that it would be permissible to terminate the Progress Contract and enter into the Reventox Contract. In addition, Integral accuses Petryna of preparing the termination letter that Progress sent to

Integral. Furthermore, Petryna allegedly advised ISTIL that it should proceed with secrecy and avoid starting a scandal. Lastly, Integral alleges that Progress ended its business relationship with Integral as a result of ISTIL's and Petryna's interference. Progress is an agency of the Ukraine government. Petryna and his associates were advising Progress and ISTIL from the Yuris Law Offices, located in Ukraine. ISTIL committed the alleged unlawful acts in Ukraine. Thus, the conduct causing the injury occurred in Ukraine.

The third factor the court must consider is the place of incorporation and place of business of the parties. In the present case, this factor does not point to any one location. Integral's place of incorporation and principal place of business is Pakistan. ISTIL's place of incorporation is Delaware. According to the complaint, ISTIL's principal place of business is Oregon. Comment e to § 145 is instructive on the importance that the court should afford this factor when evaluating it in light of the other § 145 factors: the “relative importance [of place of incorporation and place of business of the parties] varies with the nature of the interest affected.” Restatement (Second) of Conflicts of Laws § 145 cmt. e. In the case of some torts, “the importance of these contacts depends largely upon the extent to which they are grouped with other contacts. The fact, for example, that one of the parties is domiciled or does business in a given state will usually carry little weight of itself.” *Id.* Given the foregoing, the court concludes that this factor does not favor Delaware. At most, it is neutral.

\*4 The last element of § 145, the place where the relationship between the parties is centered, is inapplicable because Integral and ISTIL did not have an existing relationship.

When deciding a choice of law issue such as that before the court, “Delaware courts place considerable emphasis on ‘the place where the injury occurred’ and ‘the place where the conduct causing the injury occurred.’” *Rudisill v. Sheraton Copenhagen Corp.*, 817 F.Supp. 443, 448 n. 7 (D.Del.1993) (citations omitted). Ukraine is one of the places where the injury occurred and the place where the conduct causing the injury occurred. In addition, the place of incorporation and place of business are neutral, and the place where the relationship between the parties is centered is inapplicable. Given its analysis of the § 145 factors, the court concludes that Ukraine has the most significant relationship to the conduct about which Integral complains. Thus, the court will apply Ukrainian law. The inquiry does not end with § 145.

Not Reported in F.Supp.2d  
 Not Reported in F.Supp.2d, 2004 WL 2758672 (D.Del.)  
 (Cite as: Not Reported in F.Supp.2d)

Page 4

however, as the court must also evaluate ISTIL's acts with regard to the § 6 factors.

## 2. Section 6 Factors

Section 6 of the Restatement provides the following choice of law considerations: (a) the needs of the interstate and international systems (e.g., choice of law rules should seek to further harmonious relations and facilitate intercourse between states); (b) the relevant policies of the forum; (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue; (d) the protection of justified expectations; (e) the basic policies underlying the particular field of law; (f) certainty, predictability and uniformity of the result; and (g) ease in determination and application of the law to be applied. Restatement (Second) of Conflicts of Laws § 6. Given the principles set forth in § 6, the court finds that Ukrainian law applies to Integral's claims.

The needs of the interstate and international systems favor application of Ukrainian law. The Progress Contract was formed in order to facilitate the sale of military equipment by Progress to the Pakistani government. Ukraine has an interest in overseeing the negotiation and performance of its military contracts. Delaware has no such interest in the subject matter of the present case.

The relevant policies of the forum also favor Ukraine. Comment e to § 6 states that a court should not apply a forum state's law "where the state of the forum has no interest in the case apart from the fact that it is the place of the trial of the action." Restatement (Second) of Conflicts of Laws § 6 cmt. e. Integral has not alleged that any of ISTIL's wrongful conduct occurred in or affected Delaware. Thus, Delaware's only interest in the case is that it is the place of trial. As previously discussed, Ukraine has an interest in overseeing its military contracts. In addition, Ukraine has a criminal interest in the case-in June 2003, the Attorney General of Ukraine instituted a criminal investigation relating to the termination of the Progress Contract and related criminal acts by Progress and its director.

\*5 The third factor, the relevant policies and relative interests of the other interested states, favors Ukraine. While the forum should give consideration to its own relevant policies and the relevant policies of all other interested states, the forum should also appraise the relative interests of the states involved in the

determination of the particular issue. *Id.* cmt. f. The state whose interests are most deeply affected should have its local law applied. *Id.* Integral alleges that ISTIL interfered with its contract and its business relationship with Progress. Integral asserts further that this interference occurred in Ukraine and that Progress is an agency of the Ukrainian government. Furthermore, Integral has sought relief in Ukraine by filing a complaint with the Attorney General of Ukraine and demanding an investigation into ISTIL's and Progress' conduct. *See* Def.'s Br. at 22-23; Berman Dec. Exh. L, at 2; *id.* Exh. M, at 1. In contrast, the policies of the other interested states, particularly Delaware, are not affected. Thus, Ukraine's interests are most deeply affected, and it should have its local law applied.

The protection of justified expectations as well weighs in favor of applying Ukrainian law. "[I]t ... [is] unfair and improper to hold a person liable under the local law of one state when he had justifiably molded his conduct to conform to the requirements of another state." Restatement (Second) of Conflicts of Laws § 6 cmt. g. Assuming, as the court must, that ISTIL's conduct occurred in Ukraine, it is reasonable for the court to conclude that ISTIL had justifiably molded its conduct to conform to the requirements of Ukrainian, not Delaware, law.

The next factor the court must consider is the basic policies underlying the particular field of law. This factor is most important when differences between the policies of the interested states are not minor. The policies of Delaware and Ukraine, however, are significantly different (*i.e.* Delaware recognizes claims for tortious interference with contract and tortious interference with prospective contractual relationships, while Ukraine does not). Thus, this factor is inapplicable.

Predictability and uniformity of result favor the court's application of Ukrainian law. These factors are intended to prevent forum shopping. Integral's decision to pursue this case in Delaware, despite the fact that ISTIL's only alleged connection to the state is that Delaware is its place of incorporation, suggests that Integral is forum shopping. Moreover, as previously discussed, Integral has filed several complaints with the Attorney General in Ukraine and demanded an investigation into ISTIL's conduct in Ukraine-further evidence that Integral is forum shopping.

The final § 6 factor serves as a guideline for courts and addresses the application of choice of law rules.

Not Reported in F.Supp.2d  
 Not Reported in F.Supp.2d, 2004 WL 2758672 (D.Del.)  
 (Cite as: Not Reported in F.Supp.2d)

Page 5

It states that the rules should be simple and easy to apply. The Delaware rules are simple and easy to apply because the court only needs to determine which interested state has the most significant relationship to the issue. In the present case, pursuant to the principles enunciated in § 6, the court concludes that Ukraine has the most significant relationship to ISTIL's conduct. The court, therefore, will apply Ukrainian law to Integral's tort claims.

#### B. Integral's Tort Claims

\*6 Integral's complaint alleges violations of two common law precepts: (1) tortious interference with contract; and (2) tortious interference with prospective contractual relations. As discussed above, the court will apply Ukrainian law to Integral's claims. The law of Ukraine, however, does not recognize Integral's claims. Accordingly, the court must dismiss Integral's complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) because it does not state a cause of action under Ukrainian law. *See MM Global Serv., Inc. v. Dow Chem. Co.*, 283 F.Supp.2d 689, 704 (D.Conn.2003) (dismissing common law claims alleging tortious interference with business expectancies, Tortious interference with contractual relationships, and unfair competition because they were not actionable under Indian law); *Atlantic Richfield Co. v. ARCO-Globus Int'l Co.*, No. 95 Civ. 6361, 1996 WL 742863, at \*5 (S.D.N.Y. Dec.31, 1996).

#### ORDER

For the reasons stated in the court's Memorandum of this same date, IT IS HEREBY ORDERED that:

1. The defendant's Renewed Motion to Dismiss (D.I.47) is GRANTED.

D.Del.,2004.  
 Integral Resources (PVT) Ltd. v. Istil Group, Inc.  
 Not Reported in F.Supp.2d, 2004 WL 2758672  
 (D.Del.)

Briefs and Other Related Documents ([Back to top](#))

• [1:03cv00904](#) (Docket) (Sep. 24, 2003)

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EX. 10

Westlaw.

Slip Copy  
 Slip Copy, 2006 WL 891032 (D.Del.)  
 (Cite as: Slip Copy)

Page 1

Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court, D. Delaware.  
 ITEM DEVELOPMENT AB, Astellas U.S. LLC, and  
 Astellas Pharma US, Inc., Plaintiffs,

v.

SICOR INC. and Sicor Pharmaceuticals, Inc.,  
 Defendants.

KING PHARMACEUTICALS RESEARCH AND  
 DEVELOPMENT INC., Astellas U.S. LLC, and  
 Astellas Pharma US, Inc., Plaintiffs,

v.

SICOR INC. and Sicor Pharmaceuticals, Inc.,  
 Defendants.

No. Civ. 05-336-SLR, Civ. 05-337-SLR.

March 31, 2006.

Paul M. Lukoff, Prickett, Jones & Elliott, P.A.,  
Richard K. Herrmann, Morris, James, Hitchens &  
 Williams, Wilmington, DE, for Plaintiffs.

Karen Elizabeth Keller, Doungamon Fon Muttamara-  
Walker, Young, Conaway, Stargatt & Taylor,  
 Wilmington, DE, for Defendants.

## MEMORANDUM ORDER

ROBINSON, J.

\*1 At Wilmington this 31st day of March, 2006, having considered defendants' motions to dismiss count III of the complaint, as well as the papers submitted in connection therewith;

IT IS ORDERED that defendants' motions to dismiss count III of the complaint (Civ. No. 05-336-SLR, D.I. 5; Civ. No. 05-337-SLR, D.I. 5) <sup>FN1</sup>FN2 is granted in part and denied in part for the reasons that follow:

FN1. The D.I. numbers in this memorandum order refer to Civ. No. 05-336-SLR, unless otherwise noted.

FN2. The motions filed by defendants in Civ. No. 05-336-SLR ("the '336 case") and Civ. No. 05-337-SLR ("the '337 case") are identical, except for the parties' names and other case-specific information which is inconsequential to the resolution of these motions. The responsive arguments made by

the plaintiffs in the '337 case "mirror" those made by the plaintiffs in the '336 case. (Civ. No. 05-337-SLR, D.I.1, n. 1) Since the issues are identical and the arguments thereon are nearly identical, the court will address the issues and arguments regarding the motions in both cases in this single memorandum order.

1. Standard of Review. In analyzing a motion to dismiss pursuant to Rule 12(b)(6), the court must accept as true all material allegations of the complaint and it must construe the complaint in favor of the plaintiff. *See Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts, Inc.*, 140 F.3d 478, 483 (3d Cir.1998). "A complaint should be dismissed only if, after accepting as true all of the facts alleged in the complaint, and drawing all reasonable inferences in the plaintiff's favor, no relief could be granted under any set of facts consistent with the allegations of the complaint." *Id.* Claims may be dismissed pursuant to a Rule 12(b)(6) motion only if the plaintiff cannot demonstrate any set of facts that would entitle it to relief. *See Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957). The moving party has the burden of persuasion. *See Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir.1991).

2. With respect to their claim of infringement, plaintiffs assert that defendant Sicor Pharmaceuticals filed an ANDA and paragraph IV certification with the FDA to obtain approval for the manufacture, use and sale of Adenosine Injection, USP. (D.I. 1 at ¶ 23, 25) Plaintiffs in the '336 case assert that the use of Adenosine Injection, USP, according to its approved labeling, would "result in infringement of one or more claims of [its] '296 patent [U.S. Patent No. 5,731,296]." (D.I. 1 at ¶ 24) (Plaintiffs in the '337 case allege that the same acts would result in infringement with respect to U.S. Patent No. 5,070,877 ("the '877 patent").) Plaintiffs further allege that defendant Sicor Inc. has encouraged and induced Sicor Pharmaceuticals to file an ANDA and prepare to sell Adenosine Injection, USP pursuant to the ANDA. (D.I. 1 at ¶ 27) Count I of plaintiffs' complaint in the '336 case, entitled "Patent Infringement," restates the allegation that Sicor Pharmaceuticals infringes the '296 patent under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA to the FDA, as well as the allegation that Sicor Inc. induced Sicor Pharmaceuticals to file the ANDA

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Slip Copy, 2006 WL 891032 (D.Del.)  
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Page 2

application, prepare to sell Adenosine Injection, USP, and eventually sell it once approved by the FDA. (D.I. 1 at ¶¶ 29-30) (The same argument is offered by plaintiffs in the '337 case with respect to the '877 patent.) Count III of the complaint of plaintiffs in the '336 case, entitled "Willful Infringement," asserts in paragraph 40 <sup>FN3</sup> that the alleged infringement by defendants has been willful. (D.I. 1 at ¶¶ 38-41) (Plaintiffs in the '337 case make the same assertion in paragraph 41 of their complaint.)

<sup>FN3</sup>. "On information and belief, Defendants' infringement has been willful."  
D.I. 1 at ¶ 40.

\*2 3. Defendants move to dismiss count III of plaintiffs' complaint as failing to state a claim on which relief can be granted, pursuant to Fed.R.Civ.P. 12(b)(6). (D.I.5) Defendants assert that plaintiffs' claim in count III of their complaint, alleging willful infringement, has no support in the facts since a patentee in an infringement action under 35 U.S.C. § 271(e)(2) may not prove that an accused infringer's conduct amounts to willful infringement. (*Id.*)

4. Plaintiffs argue that defendants' arguments with respect to § 271(e)(2) are incorrect and ignore the facts of this case. (D.I. 14 at 2-6) Furthermore, plaintiffs request that the court not strike those portions of count III which are not directed to willful infringement. (*Id.* at 6-7)

5. The Federal Circuit initially addressed the issue of willfulness in ANDA and paper NDA cases in Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339 (Fed.Cir.2000). In *Yamanouchi*, the court noted that "[a]n ANDA [or paper NDA] filing by its very nature is a 'highly artificial act of infringement,' therefore, the trial court need not have elevated the ANDA certification into a finding of willful infringement." 231 F.3d at 1347. Nevertheless, the court held that the case was exceptional and awarded attorney's fees to the plaintiff, based on defendant's "misconduct in filing a wholly unjustified ANDA certification and misconduct during the litigation that followed...." *Id.*

6. The Federal Circuit addressed this issue again in Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339 (Fed.Cir.2004), holding that "the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)." 376 F.3d at

1350-51. The court noted that in *Yamanouchi*, it had "determined that a baseless and 'wholly unjustified' paragraph IV certification in an ANDA filing, when combined with litigation misconduct, warranted an exceptional case finding." *Id.* at 1350. The court continued, "in *Yamanouchi*, we did not agree that the generic company had engaged in willful infringement, but rather determined that an award of attorney's fees was permitted because the generic had filed numerous baseless filings supporting its fruitless and meritless arguments, both in its case at trial and in its ANDA certification." *Id.*

7. In the case at bar, plaintiffs have not offered any support for a finding of willful infringement. The only allegations of infringement by plaintiffs are that Sisor Pharmaceuticals filed an ANDA and paragraph IV certification for Adenosine Injection, USP, and that Sisor Inc. assisted, induced or encouraged Sisor Pharmaceuticals in those and related acts. Because the filings of Sisor Pharmaceuticals cannot support a claim of willful infringement, plaintiffs' complaint fails to state a claim on that basis. Paragraph 40 of count III of the complaint in the '336 case, and paragraph 41 of count III of the complaint in the '337 case, shall be dismissed. Plaintiffs assert that, even if the court strikes the allegations of willful infringement in count III, the allegations concerning exceptional case and attorney's fees should remain. The court agrees. As the Federal Circuit explained in *Glaxo*, a finding that a ANDA/paper NDA case is "exceptional" can be based on meritless filings combined with litigation misconduct, although a finding of willful infringement cannot. Glaxo, 376 F.3d at 1350-51. Plaintiffs shall have the opportunity to establish facts which support a claim for an exceptional case for which the court may award attorney's fees. Thus, the remaining paragraphs of count III (¶¶ 38, 39, 41 in the '336 case; ¶¶ 39, 40, 42 in the '337 case), including those relating to an exceptional case and attorney's fees, shall not be dismissed.

D.Del.,2006.  
Item Development AB v. Sisor Inc.  
Slip Copy, 2006 WL 891032 (D.Del.)

Briefs and Other Related Documents ([Back to top](#))

- 2006 WL 809191 (Trial Motion, Memorandum and Affidavit) Sisor's Objections to Second Notice of Deposition of Sisor Inc. and Sisor Pharmaceuticals, Inc. Pursuant to Fed. R. Civ. P. Rule 30(b)(6) (Feb. 27, 2006)
- 2006 WL 809192 (Trial Motion, Memorandum and

Slip Copy  
Slip Copy, 2006 WL 891032 (D.Del.)  
(Cite as: Slip Copy)

Page 3

Affidavit) Sicor's Objections to First Notice of Deposition of Sicor Inc. and Sicor Pharmaceuticals, Inc. Pursuant to Fed. R. Civ. P. Rule 30(b)(6) (Feb. 27, 2006)

- 2006 WL 809193 (Trial Motion, Memorandum and Affidavit) Sicor's Objections to First Notice of Deposition of Sicor Inc. and Sicor Pharmaceuticals, Inc. Pursuant to Fed. R. Civ. P. Rule 30(b)(6) (Feb. 27, 2006)

- 2006 WL 809194 (Trial Motion, Memorandum and Affidavit) Sicor's Objections to Second Notice of Deposition of Sicor Inc. and Sicor Pharmaceuticals, Inc. Pursuant to Fed. R. Civ. P. Rule 30(b)(6) (Feb. 27, 2006)

- 2005 WL 2603683 (Trial Motion, Memorandum and Affidavit) Defendants Sicor inc. and Sicor Pharmaceuticals Inc.'s Reply in Support of Their Motion to Dismiss Count III of the Complaint (Sep. 6, 2005)

- 2005 WL 2603685 (Trial Motion, Memorandum and Affidavit) Defendants Sicor Inc. and Sicor Pharmaceuticals Inc.'s Reply in Support of Their Motion to Dismiss Count III of the Complaint (Sep. 6, 2005)

- 2005 WL 2603684 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Memorandum in Opposition to Defendants' Motion to Dismiss Count III of the Complaint (Aug. 29, 2005)

- 2005 WL 2603857 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Memorandum in Opposition to Defendants' Motion to Dismiss Count III of the Complaint (Aug. 29, 2005)

- 2005 WL 1529897 (Trial Pleading) Complaint for Patent Infringement (May 26, 2005)

- 2005 WL 1529898 (Trial Pleading) Complaint for Patent Infringement (May 26, 2005)

- 1:05cv00337 (Docket) (May 26, 2005)

- 1:05cv00336 (Docket) (May 26, 2005)

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EX.11

1

1 UNITED STATES DISTRICT COURT  
2 DISTRICT OF NEW JERSEY  
3 CIVIL ACTION NO. 3:04-1689 (MLC)

4 ORTHO-McNEIL PHARMACEUTICAL, INC., ORAL ARGUMENT

5 Plaintiff and  
6 Counterclaim Defendant,

7 vs.

8 MYLAN LABORATORIES, INC. and  
9 MYLAN PHARMACEUTICALS, INC.,

10 Defendant and  
11 Counterclaim Plaintiffs

12 April 18, 2005  
13 Trenton, New Jersey

14 B E F O R E: HONORABLE STANLEY R. CHESLER, USDJ

15

16

17 Pursuant to Section 753 Title 28 United States Code, the  
18 following transcript is certified to be an accurate record  
19 as taken stenographically in the above-entitled proceedings.

20 JACQUELINE KASHMER  
21 Official Court Reporter

22

23

24 JACQUELINE KASHMER, C.S.R.  
25 OFFICIAL COURT REPORTER  
P. O. Box 12  
Pittstown, NJ 08867  
(609) 656-2595

1  
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JEFFREY SOOS, ESQ.,  
For the Defendants

1 THE COURT: Ortho-McNeil Pharmaceutical vs. Mylan.

2 Can I have appearances by counsel please.

3 MR. ROPER: For Ortho-McNeil, Harry Roper, Aaron

4 Barlow and Eric Lohrenz,

5 MR. MIDDLETON: And also John Middleton from

6 Lowenstein Sandler, your Honor.

7 THE COURT: Good morning.

8 MR. CALMANN: Arnold Calmann, Saiber, Schlesinger,

9 Satz & Goldstein, for the defendants, Mylan, and with, me

10 your Honor, are my co-counsel David Harth and Shannon

11 Bloodworth from the Heller Ehrman firm.

12 THE COURT: Good morning to you. We will first

13 take the motion to dismiss the willful infringement claim

14 I'll hear from counsel for movant.

15 MR. HARTH: Thank you, your Honor. The motion

16 simply asks the Court to apply recent binding Federal

17 Circuit precedent that the filing of an ANDA application or

18 certification cannot support a finding of willful

19 infringement.

20 The Federal Circuit in the Glaxo case held that

21 willfulness cannot provide the basis for the filing of an

22 ANDA certification, cannot provide the basis for a

23 willfulness claim.

24 The plaintiffs here have contended that Glaxo does

25 not apply because in that case the defendant had not filed a

1 Paragraph 4 certification, which is what happened here, but  
2 the Federal Circuit crafted its holding in Glaxo  
3 specifically to cover Paragraph 4 certifications.

4 In that case the Federal Circuit held, quote, "The  
5 mere fact that a company has filed an ANDA application or  
6 certification cannot support a finding of willful  
7 infringement for the purpose of awarding attorney's fees  
8 pursuant to 35 U.S.C. Section 271", and the Federal Circuit  
9 did so on the basis of the Yamanouchi case, which was a  
10 Paragraph 4 certification.

11 Since the Federal Circuit's decision in Glaxo, the  
12 precise issue that's presented here was decided by the  
13 District of Massachusetts in Aventis vs. King  
14 Pharmaceuticals, and prior to the last hearing we had sent  
15 Judge Cooper a letter with that case. Is that in the  
16 Court's file?

17 THE COURT: I do have the Aventis vs. Cobalt  
18 Pharmacy.

19 MR. HARTH: Well, Aventis rejected the very  
20 argument that Ortho-McNeil is making here holding that the  
21 words "or certification" in the Federal Circuit's Glaxo  
22 decision was not mere surplusage, that it did cover  
23 Paragraph 4 certification cases, and for that reason there  
24 could be no willfulness claim in a Paragraph 4 certification  
25 case, either.

1 We think that the District of Massachusetts got it  
2 right. We think that the Federal Circuit's language is  
3 unambiguous in that regard and for that reason, the  
4 willfulness claim should be dismissed.

5 THE COURT: Let me hear from counsel for the  
6 plaintiffs.

7 MR. ROPER: Harry Roper for the plaintiffs, your  
8 Honor. I think that our position on this Glaxo case is not  
9 controlling. This has not been definitively ruled upon by  
10 the Federal Circuit because in Glaxo there was no Paragraph  
11 4 certification.

12 Here our whole contention is that the Paragraph 4  
13 certification is so baseless and the lawsuit is so baseless  
14 that the infringement which is virtually admitted is  
15 willful.

16 The Massachusetts case that they cite, of course,  
17 is not precedential because the Federal Circuit hasn't ruled  
18 on it. So, that being said, your Honor, this is a bench  
19 trial. I think this law may develop further in the Federal  
20 Circuit and my suggestion is that your Honor defer this  
21 entire thing and we see how that law develops.

22 Basically, our contention here is that in light of  
23 this case, we are entitled to attorney's fees one way or the  
24 other in this case and either it's willful infringement or  
25 it's under the statute and we are entitled to them. And we

1 are entitled to discovery. Whether that discovery gets  
2 bifurcated or not is not important. But I think  
3 fundamentally we don't see any reason why there can't be a  
4 willful infringement case in ANDA litigation.

5 THE COURT: So, your argument is that the Fed  
6 Circuit's opinion in Glaxo vs. Apotex, where they say,  
7 quote, "Consequently, as suggested by Yamanouchi, we now  
8 hold that the mere fact that a company has filed an ANDA  
9 application or certification cannot support a finding of  
10 willful infringement for purposes of awarding attorney's  
11 fees pursuant to 35 U.S.C. Section 271(e)(4). The Supreme  
12 Court has emphasized that 35 U.S.C. Section 271(e)(2) and 35  
13 U.S.C. Section 271(e)(4) create a 'artificial act of  
14 infringement' only for a 'very limited and technical  
15 purpose' that relates only to certain drug applications."

16 MR. ROPER: Two reasons.

17 THE COURT: Why would a poor soul like me working  
18 in the trenches conclude that the Federal Circuit didn't  
19 mean what they said there?

20 MR. ROPER: They did mean what they said there.

21 THE COURT: Okay.

22 MR. ROPER: And they say the mere fact that you  
23 filed ANDA, that's different than filing a baseless ANDA,  
24 number one, and it's certainly different than filing a  
25 baseless Paragraph 4 certification, which they didn't even

1 deal with in that case, so, our facts are different than  
2 Glaxo for those two reasons, your Honor.

3 THE COURT: Okay. I must tell you that as  
4 interesting as I find your argument, I find that it goes  
5 fundamentally against the underlying rationale of the Fed  
6 Circuit's decision in the Glaxo case.

7 Their emphasis was on the fact that this whole  
8 Hatch-Waxman process exists for a very limited purpose of  
9 creating a technical infringement so that a case or  
10 controversy under the Constitution can exist whereby United  
11 States district courts and other folk who decide these cases  
12 can actually decide whether or not the proposed generic  
13 drug, if manufactured, would infringe. And as I read the  
14 Glaxo case, it's saying where the whole reason that we, in  
15 fact, permit a case to go forward as an infringement case  
16 because of this technical infringement is to permit the  
17 matter to be decided before the drug gets on the market;  
18 that the mere filing of that ANDA application or  
19 certification can't constitute a willful infringement.

20 What the court in Glaxo makes clear, as I  
21 understand, is that doesn't mean that the plaintiff can't  
22 apply for attorney's fees but they're not applying for  
23 attorney's fees on the basis of a willful infringement.  
24 They're applying for attorney's fees on the basis of it  
25 being, I believe it would be an extraordinary case. Is that

1 correct?

2 MR. ROPER: Yes, your Honor, that's correct.

3 THE COURT: And as I understand it, in Glaxo they  
4 said, go ahead, go for it under that standard but not under  
5 a willful infringement standard. Correct?

6 MR. ROPER: Yes, your Honor. Except that they  
7 didn't deal, as I said, with the specific facts that we have  
8 here.

9 THE COURT: Go ahead. I'm sorry.

10 MR. ROPER: And your Honor, and indeed, as I said,  
11 that our only position here is to preserve our right to seek  
12 those attorney's fees one way or the other and, to be quite  
13 frank, your Honor, if your Honor would permit, we would  
14 withdraw the actual willfulness claim as long as we're  
15 permitted to continue to seek discovery and continue to  
16 pursue the claim under the statute.

17 THE COURT: Well, there's no doubt that you can  
18 seek to pursue attorney's fees under an extraordinary case  
19 standard, I must tell you, all right, but — and I  
20 understand exactly where you're going, all right, and the  
21 short answer is no. Okay.

22 I will tell you, if the issue is can we engage in  
23 all sorts of discovery for a willful infringement standard  
24 because — let me put it this way — because if willful  
25 infringement stays in the case, then they're going to assert

1 a defense of reasonable reliance of advice of counsel and  
2 then we can say we get the right to take a look at all your  
3 opinion letters and so on and so forth because there's a  
4 reliance on advice of counsel defense. Correct?

5 MR. ROPER: Your Honor, can I make a comment on  
6 that specifically?

7 THE COURT: Yes.

8 MR. ROPER: It's a good point. Your Honor, there  
9 is a dispute right now, a discovery dispute with regard to  
10 whether we are entitled to get their counsel's opinion for  
11 this reason; that during testimony there was a lot of -- I  
12 don't want to argue the motion to get the opinion --

13 THE COURT: That's good because the magistrate  
14 judge is going to be hearing that particular application.

15 MR. ROPER: And we are going to present -- and we  
16 will present that to her. It's been discussed by the  
17 parties but we are going to be presenting it to her and  
18 that's for that. So, and we are satisfied to live with that  
19 ruling.

20 I'm not seeking anything other than that. We would  
21 be happy to live with that ruling without regard to  
22 willfulness, simply with regard to waiver.

23 THE COURT: Okay. First, I'm satisfied that  
24 Glaxo's language is not mere surplusage and to the extent  
25 that the Glaxo opinion contains the word "or certification"

1 is dicta. The Court will regard it as dicta which gives a  
2 very clear and forceful direction to the district court as  
3 to how the Federal Circuit views this particular claim.

4 The Court is satisfied that the Glaxo opinion of  
5 the Fed Circuit, indeed, as interpreted by U.S. District  
6 Court for the District of Massachusetts in Aventis Pharma  
7 Deutschland GMBH and King Pharmaceuticals vs. Cobalt  
8 Pharmaceuticals reported at 2005 Westlaw 289835, in fact,  
9 correctly interprets Glaxo and the willful infringement  
10 claim is dismissed. Okay.

11 And by the way, what I was saying is that I  
12 sometimes sit and for some reason I'm amazed at what is  
13 almost a prurient interest which patent counsel have in  
14 looking at the opinions of each other and while I understand  
15 the curiosity, the Court nevertheless does not have to  
16 encourage it. Okay.

17 MR. ROPER: Thank you, your Honor.

18 THE COURT: Now, we've got a motion for summary  
19 judgment. Correct?

20 MR. HARTH: We do, your Honor.

21 THE COURT: All right. And in the first instance  
22 that hinges on a Markman interpretation. Correct?

23 MR. HARTH: Yes, your Honor.

24 THE COURT: Okay. Let me hear you.

25 MR. HARTH: This basically is the Markman part of

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

ORTHO-McNEIL PHARMACEUTICAL,  
INC.,

Plaintiff

v.

MYLAN LABORATORIES, INC.,  
et al.,

Defendants.

Hon. Stanley R. Chesler  
Civil Action No. 04-1689

ORDER

CHESLER, U.S. District Court Judge

THIS MATTER comes before the Court upon Defendants' Motion for Judgment on the Pleadings Dismissing Plaintiff's Claim of Willfulness (docket item #16), and Defendants' Motion for Summary Judgment of Non-Infringement (docket item #22). The Court having considered the papers submitted by the parties, having heard oral argument, and for the reasons set forth in the record of oral argument on April 18, 2005;

IT IS on this 18th day of April 2005:

ORDERED that Defendants' Motion to Dismiss Plaintiff's Claim of Willfulness is GRANTED; and it is further

ORDERED that judgment is RESERVED on Defendants' Motion for Summary Judgment; and it is further

ORDERED that the parties are directed to contact the Court  
to schedule a Markman hearing.

s/  
STANLEY R. CHESLER  
U.S. District Court Judge

EX. 12

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

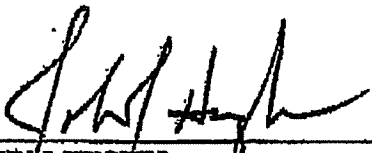
ORTHO-MCNEIL, et al., : Civil Action No.: 02-2794(GEB)  
: :  
Plaintiffs, : :  
: :  
v. : :  
: : **ORDER**  
TEVA PHARMACEUTICALS USA, : :  
: :  
Defendant. : :  
\_\_\_\_\_ :

This matter having come before the Court upon Motion of the Defendant Teva Pharmaceuticals USA to Bifurcate Trial and to Stay Discovery [Docket entry #22], returnable December 2, 2002; and Plaintiffs having submitted Opposition and a Sur-Reply; and Defendant having submitted a Reply; and the Court having reviewed all parties' submissions and considered the matter pursuant to FED. R. CIV. P. 78; and for the reasons stated in the accompanying Memorandum Opinion; and good cause having been shown;

IT IS on this 25<sup>th</sup> day of January, 2003,

ORDERED that Defendant Teva Pharmaceuticals USA's Motion to Bifurcate Trial and to Stay Discovery is granted; and it is

FURTHER ORDERED that discovery on willfulness is hereby stayed and trial on Liability and willfulness will be bifurcated.

  
\_\_\_\_\_  
JOHN J. HUGHES  
UNITED STATES MAGISTRATE JUDGE

FROM

ORIGINAL FILED

NOT FOR PUBLICATION

JAN 30 2006

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

WILLIAM T. WALSH, CLERK

ORTHO-MCNEIL, et al.,

Civil Action No.: 02-2794(GEB)

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA,

MEMORANDUM OPINION

Defendant.

HUGHES, U.S.M.I.

This matter is before the Court upon the Motion of the Defendant, Teva Pharmaceuticals USA ("Defendant or Teva"), to Bifurcate Trial and to Stay Discovery pursuant to FED. R. CIV. P. 42(b). Plaintiffs, Ortho-McNeil Pharmaceutical, Inc., Johnson & Johnson, Pharmaceutical Research & Development, LLC, and Daiichi Pharmaceutical, Co., Ltd. ("Plaintiffs") oppose the Motion. The Court has reviewed the written submissions of the parties and considered the matter pursuant to FED. R. CIV. P. 78. For the reasons that follow, the Defendant's Motion is granted.

I. BACKGROUND AND PROCEDURAL HISTORY

Plaintiff, Daiichi Pharmaceutical Co., Ltd. is the owner of the '407 patent, known as Levaquin® that was licensed to Plaintiffs, Ortho-McNeil Pharmaceutical, Inc. and Johnson & Johnson Pharmaceutical Research and Development, LLC. Defendant Teva filed an abbreviated new drug application ("ANDA") with the United States Food and Drug Administration ("FDA") in order to obtain approval to manufacture and market drug products containing levofloxacin. The ANDA included a Paragraph IV Certification asserting Teva's opinion that the '407 patent

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was invalid, unenforceable, or not infringed. Subsequent to Teva's filing an ANDA, Plaintiffs filed the present action as authorized by 35 U.S.C. § 271(e)(2).

In the present action, Plaintiffs allege that Teva willfully infringed its U.S. Patent No. 5,053,407 ("the '407 patent") when Teva submitted an ANDA with the United States FDA in order to obtain approval to manufacture and market a generic version of Levaquin®. Specifically, Plaintiffs allege that Defendant's infringement of its Patent '407 is willful because Defendant was "[f]ully aware that a valid and enforceable patent protect[ed] the LEVAQUIN® products. . . [when it] deliberately created copies of [them] . . . ." (Pls.['] Br. at 2).

Teva challenges the validity of the '407 patent, owned by Plaintiff, Daiichi Pharmaceutical Co., Ltd. and argues that the patent is invalid. Teva has filed counterclaims seeking a declaration that the '407 patent is invalid and an award of attorney's fees. Additionally, Defendant states that it has yet to market or sell any product containing the ingredient in issue, and thus, there are no damages, nor are any damages sought by the Plaintiffs. Therefore, Teva brings the present Motion seeking an Order from this Court bifurcating trial and staying discovery on the willful infringement issue, arguing that separating the liability issue of validity from willfulness will promote efficiency, convenience and prevent prejudice. (Def.['s] Br. at 1).

On the other hand, Plaintiffs contend that bifurcation is the exception and not the rule in patent cases and where the issues of liability and willful infringement are intertwined, as here, the moving party has the burden of showing why bifurcation is necessary. Of course, Plaintiffs argue that Defendant has failed to meet the necessary burden to bifurcate trial and stay discovery on the issue of willful infringement. Defendant challenges Plaintiffs' position that liability and willful

FROM

infringement are intertwined and argues that willful infringement is "relevant only to the issue of attorney's fees pursuant to 35 U.S.C. § 285 . . . ." (*Id.* at 3). Therefore, Defendant argues that the issues of liability and willful infringement can fairly be separated for trial purposes.

In addition to the issues of liability and willful infringement being intertwined, Plaintiffs argue that bifurcating trial will impose unnecessary delay and burden upon the parties because of the costs of additional discovery, preparation, and trial. (Pls.['] Br. at 3, 6). To the contrary, Defendant argues that bifurcating trial and staying discovery on the willfulness issue will promote efficiency as well as judicial economy and offers three arguments to support its position. First, Defendant argues that should the '407 patent be found invalid, there will be no need for discovery or fact-finding on the willfulness issue because there would necessarily be no infringement, willful or otherwise. Second, Defendant contends that even if the '407 patent is found to be valid, a determination of willful infringement is relevant only to the issue of awarding attorney's fees. Lastly, Defendant asserts that attorney's fees are awarded only in exceptional cases of willful infringement and here, where there are no damages, there cannot be such a finding.

More importantly, Defendant argues that bifurcating trial and staying discovery will avoid the need for it to prematurely decide whether to waive attorney-client privilege in order to defend allegations of willfulness when the prevailing party on the invalidity issue has yet to be determined. Plaintiffs challenge Defendant's argument by reasserting that (1) bifurcation of trial will cause unnecessary delay and duplication of evidence and (2) the risk of disclosing privilege prematurely is a conflict that Defendant, itself, created when it used the same law firm for trial and opinion. Thus, Plaintiffs argue that the conflict created by Defendant itself does not justify

FROM

bifurcation. Nevertheless, Defendant requests bifurcation of trial and staying discovery on the willful infringement issue because without it, it would otherwise cause a significant risk of unfair prejudice. (See Def.'s Mem. at 11).

## II. DISCUSSION

Pursuant to FED. R. CIV. P. 42(b), a court may bifurcate a trial if it would be "in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy[.]" FED. R. CIV. P. 42(b). "[T]he decision to bifurcate . . . is a matter to be decided on a case-by-case basis and must be subject to an informed discretion by the trial judge in each instance." *Lis v. Robert Packer Hospital*, 579 F.2d 819, 824 (3d Cir. 1978), *cert. denied*, 429 U.S. 955 (1978). The moving party has the burden of demonstrating that judicial economy would best be served by bifurcating the case, and that no party would be unduly prejudiced by having separate trials. *Princeton Biochemicals, Inc. v. Beckman Instruments, Inc.*, 180 F.R.D. 254, 256 (D.N.J. 1997); *Spectra-Physics Lasers, Inc. v. Uniphase Corp.*, 144 F.R.D. 99, 101 (N.D.Cal. 1992).

Bifurcation would be unwarranted if it would result in duplication of effort, inconvenience to the parties and the Court, undue delay, unreasonable expense, or prejudice. *Princeton Biochemicals, Inc.*, 180 F.R.D. at 256; *Johns Hopkins University v. Cellpro*, 160 F.R.D. 30, 32 (D.Del. 1995).

### A. Bifurcating Liability

Federal courts have bifurcated patent cases when the party seeking bifurcation has demonstrated that the issues are complex and would involve the presentation of extensive evidence, which could result in jury confusion and prejudice to the parties. *Princeton*

FROM

*Biochemicals, Inc.*, 180 F.R.D. at 257; *Spectra-Physics Lasers, Inc.*, 144 F.R.D. at 101; *B. Braun Medical Inc. v. Abbou Laboratories*, 1994 WL 468155, at \*1 (E.D.Pa. August 24, 1994).

In *Smith v. Alyeska*, the court noted:

In the normal case separate trial of issues is seldom required, but in a patent infringement suit considerations exist which suggest that efficient judicial administration would be served by separate trials on the issues of liability and damages. The trial of the damages question in such a suit is often difficult and expensive, while being easily severed from the trial of the questions of validity and infringement of the patent. A preliminary finding on the question of liability may well make unnecessary the damages inquiry, and thus result in substantive saving of time of the Court and counsel and reduction of expense to the parties. Moreover, separate trial of the issue of liability may present counsel the opportunity to obtain final settlement of that issue or appeal without having reached the often time-consuming and difficult damages question.

*Smith v. Alyeska*, 538 F.Supp. 977, 982-83 (D.Del. 1982), *aff'd*, 758 F.2d 664 (Fed. Cir. 1984), *cert. denied*, 471 U.S. 1066 (1985) (quoting *Swafford v. B & W, Inc.*, 34 F.R.D. 15, 19-20 (S.D. Tex. 1963) *aff'd*, 336 F.2d 406 (5<sup>th</sup> Cir. 1964), *cert. denied*, 379 U.S. 962 (1965)).

In the present case, the Court finds that the issues are not necessarily complex, as it involves only one patent, specifically, the '407 patent. Additionally, there are no issues of damages to be resolved because there has been no marketing or sale of the product. Nevertheless, courts have considered and balanced other factors such as the prejudice that may be caused for a party should bifurcation not be ordered. See FED. R. Civ. P. 42(b). Here, the Court finds that while the validity of the patent at issue is not complex, the issue of "liability and willfulness are two distinct causes of action" as the court found in *Princeton Biochemicals, Inc.*, and thus have different elements which must be proved. *Princeton Biochemicals, Inc.*, 180 F.R.D. at 258 fn.3. Moreover, the Court finds that at this juncture, the potential prejudice to the

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Defendant outweighs the potential waste of resources as the Plaintiffs suggest. Accordingly, the Court is unconvinced that there would be any substantial overlap or duplicity as a result of bifurcating trial and discovery with regards to liability and willfulness. Lastly, the Court agrees with the Defendant that once the validity of the patent is determined and infringement is or is not found, then the Court can speedily proceed with its determination of willfulness. Furthermore, the Court finds that bifurcation, while certainly not the rule but the exception, would nevertheless, promote efficiency and judicial economy in this particular case.

**B. Willful Infringement and Exceptional Case Issue**

Defendant moves to bifurcate and stay discovery on the willful infringement/exceptional case issue arguing that a determination of the validity of the '407 patent will provide more focus as to discovery on the willful infringement/exceptional case issue. Defendant contends that there is no need to expend additional resources and burden parties regarding damages when Plaintiffs did not even seek damages in the present case. The Court agrees with the Defendant that conducting discovery on issues surrounding willful infringement is premature at this point, especially, when no damages have been sought by the Plaintiffs. Accordingly, there is no need at this time to determine willful infringement and even more so, the exceptional case issue which is related to a finding of willful infringement.<sup>1</sup> Therefore, the Court finds that a two-step process of

---

<sup>1</sup>Both Plaintiffs and Defendant have requested an award of attorneys' fees should either prevail in the lawsuit. An award of attorneys' fees in patent cases is granted only in exceptional cases where the infringement was found to be willful. However, a finding of willful infringement does not automatically mandate a court to award attorneys' fees. *Whelan v. A. Ward Enterprises, Inc.*, 2002 WL 1745614, at \* 5 (E.D.Pa. July 23, 2002) (citing *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826 (Fed. Cir. 1992)). There are nine factors that the *Read* Court listed in determining whether to award an attorney's fees in patent infringement cases. *Read*, 970 F.2d at 827. At this time, the Court finds it unnecessary to even review those nine factors.

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determining first the liability and then damages, if any, will not deter efficiency and judicial economy.

More importantly, the Court is persuaded by Defendant's argument that the issue of willful infringement should be bifurcated because discovery on that issue would involve the disclosure of attorney-client communications. In *Quantum v. Tandon*, 940 F.2d 642, 643-44 (Fed. Cir. 1991) the Court stated:

Proper resolution of the dilemma of an accused infringer who must choose between the lawful assertion of the attorney-client privilege and avoidance of a willfulness finding if infringement is found, is of great importance not only to the parties but to the fundamental values sought to be preserved by the attorney-client privilege. An accused infringer, therefore, should not, without the trial court's careful consideration, be forced to choose between waiving the privilege in order to protect itself from a willingness finding, in which case it may risk prejudicing itself on the question of liability, and maintaining the privilege, in which case it may risk being found to be a willful infringer if liability is found. Trial courts thus should give serious consideration to a separate trial on willfulness whenever the particular attorney-client communications, once inspected by the court, *in camera*, reveal that defendant is indeed confronted with this dilemma.

*Id.* at 644; see also *Princeton Biochemicals, Inc.*, 180 F.R.D. at 259. As federal courts in this District have properly held, "willful infringement is more appropriately determined after liability has been established, thereby avoiding even the possibility of prejudice to a patent defendant's litigation rights." *Princeton Biochemicals, Inc.*, 180 F.R.D. at 258.

Moreover, the Court is unconvinced at this juncture that the proofs required to demonstrate Defendant's willfulness, when it infringed against Plaintiffs' patent '407, are intertwined with the proofs regarding the validity of the patent. Accordingly, the Court cannot foresee that there will be any significant overlapping of evidence. In addition, as the parties have

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pointed out the fact that there is only one patent at issue in the present litigation should minimize any substantial duplication of evidence which might have increase costs. More importantly, the Court is mindful of the fact that allowing Plaintiffs to pursue discovery on the willful infringement issue may cause Defendant to prematurely waive its attorney-client privilege thereby possibly prejudicing its case. Therefore, the Court finds that bifurcating trial and staying discovery as to the issue of willful infringement/exceptional case is appropriate in this particular case.

### III. CONCLUSION

For the reasons stated above, Defendant Teva Pharmaceuticals' Motion to Bifurcate Trial and Stay Discovery on the Willful Infringement/Exceptional Case Issue is granted. Discovery on willfulness is stayed and shall commence after the parties conduct a meeting and confer pursuant to FED. R. CIV. P. 26(f) to determine the timing and parameters of such discovery. In addition, trial on liability and willfulness will be bifurcated.

An appropriate Order accompanies this Memorandum Opinion.

Dated:

January 28, 2003

EX. 13

## Westlaw.

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(Cite as: Not Reported in F.Supp.)

Page 1

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### Briefs and Other Related Documents

Only the Westlaw citation is currently available.  
United States District Court, C.D. California  
SAGE PRODUCTS, INC., Plaintiff,  
v.  
DEVON INDUSTRIES, INC., Defendant.  
CV 93-2403 RG (CTX).

Jan. 25, 1994.

William M. Lee, Jr., Jeffrey Robert Gray, Lee MannSmith McWilliams, Sweeney & Ohlson, William T. Cahill, Phelan Pope Cahill & Devine, Chicago, IL, for plaintiff.

Robert C. Weiss, Kenneth H. Ohriner, David A. Randall, Lyon & Lyon, Los Angeles, CA, Mitchell D. Raup, Mayer Brown & Platt, Eric F. Greenberg, George Edward Bullwinkel, Bullwinkel Partners Ltd., Chicago, IL, for Devon Indus. Inc.

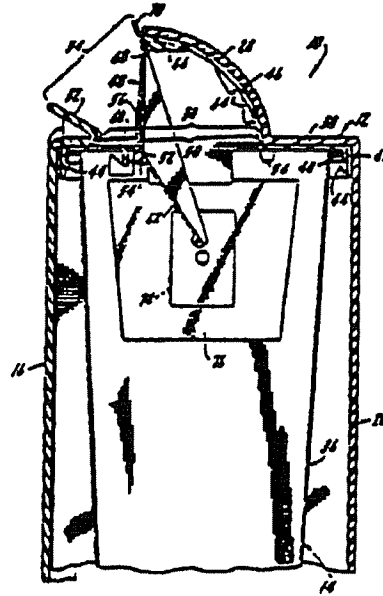
Memorandum and Order Granting Defendant's Motion for Partial Summary Judgment and Motion for Bifurcation.

GADBOIS, District Judge.

### *I. Background*

\*1 Plaintiff Sage Products, Inc. ("Sage") produces receptacles for safe disposal of used syringes, scalpels, and other hazardous medical waste, called "sharps disposal containers". Sage owns U.S. Patent Re 33,413 ('413), which covers the disposal container

shown in Figure 1.

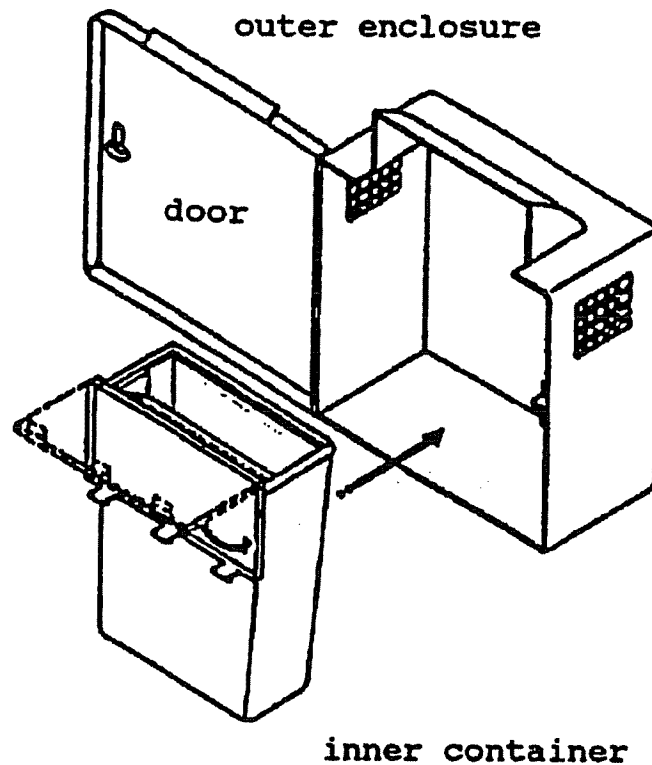


**Figure 1**

As Figure 2 shows, the '413 system consists of an outer enclosure and an inner container. The outer enclosure is a simple box structure, permanently mounted on a hospital wall, with a swinging door. When the door is open, hospital staff can place the inner container inside the outer enclosure.

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(Cite as: Not Reported in F.Supp.)

Page 2



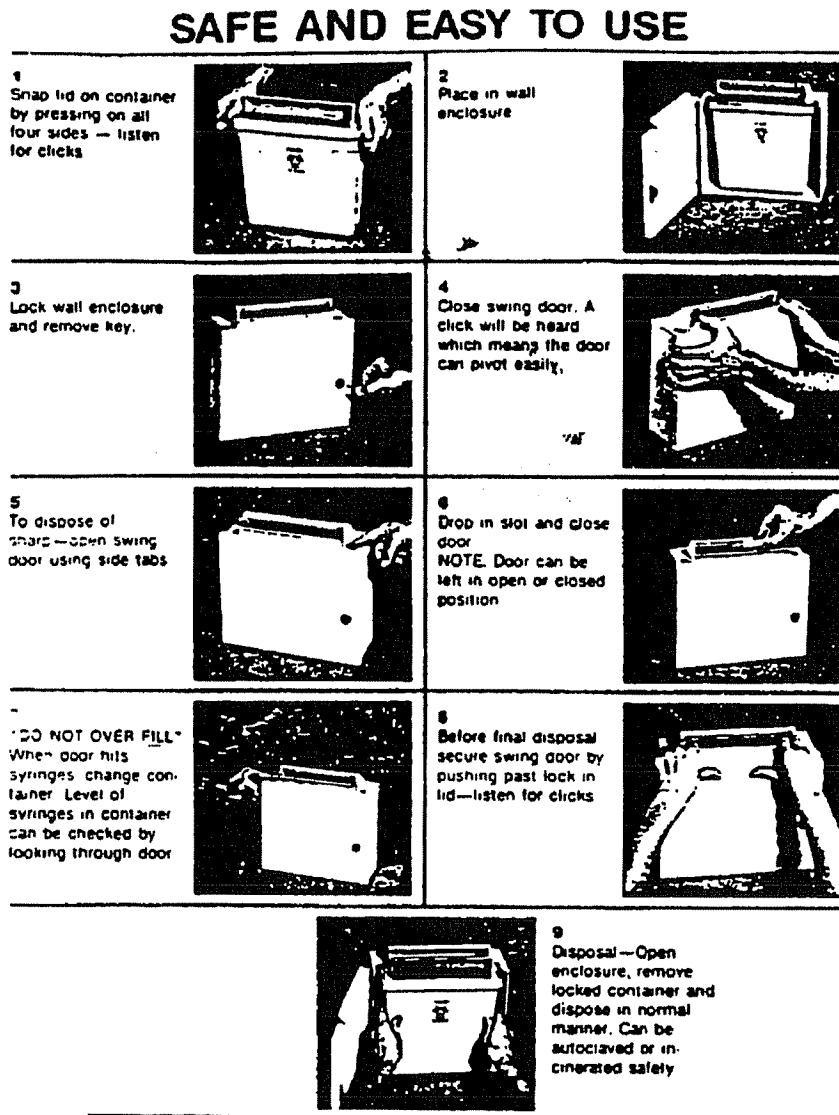
**Figure 2**

When the inner container is in place and the outer enclosure door closed, hospital staff drop sharps and other medical waste through the opening in the outer enclosure. Once the inner container is full, it is

removed, and then usually autoclaved (heated under pressure) to neutralize infectious waste, or simply incinerated. Figure 3, taken from a Sage brochure, shows how the system is used.

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 (Cite as: Not Reported in F.Supp.)

Page 3



**Figure 3**

Defendant Devon Industries, Inc. ("Devon") manufactures inner containers compatible with Sage's '413 system. Sage alleges that Devon contributorily infringes the '413 patent by selling replacement inner containers to hospitals. On January 10, 1994, Devon moved for partial summary judgment, contending that its inner containers are used for permissible repair, not infringing reconstruction, of the '413 system.

Devon also moved for bifurcation, seeking to have the issues of damages and willfulness tried separately from the issues of validity and infringement.

## II. Jurisdiction

This Court has jurisdiction under 28 U.S.C. § § 1331, 1338(a).

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 (Cite as: Not Reported in F.Supp.)

Page 4

### III. Analysis

#### a. Defendant's Motion for Summary Judgment.

Replacement of worn or spent parts of a patented combination is permissible repair of the combination, not infringing reconstruction. *Everpure, Inc. v. Cuno, Inc.*, 875 F.2d 300, 303 (Fed. Cir. 1989), *cert. denied*, 493 U.S. 853 (1989); *Porter v. Farmers Supply Serv., Inc.*, 790 F.2d 882, 886 (Fed. Cir. 1986). Defendant argues that once the inner containers are filled with waste, they are spent. Therefore, it contends, replacing the containers is permissible repair of the '413 system, not infringement. See *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 341 (1961); *Everpure*, 875 F.2d at 303 (holding that replacement of a disposable cartridge, which housed a filter, constituted repair, not reconstruction).

Sage replies that the inner container is neither spent nor worn when it is filled with waste, but rather merely in need of emptying. Hanifl aff. ¶ 5. Sage contends that filled inner containers are perfectly salvageable, and therefore, replacing them is impermissible *reconstruction* of the '413 combination.

This Court rejects this argument. Emptying and reusing filled inner containers defeats the purpose of the '413 combination -- safe disposal of hazardous waste. Sage itself recognizes this, and encourages their customers to dispose of the inner containers for safety's sake. Hanifl Dep. 119:11-22. In fact, Sage's own inner containers are labeled "Single Use Only", and ominously warn of the biohazard within. See Figure 4.

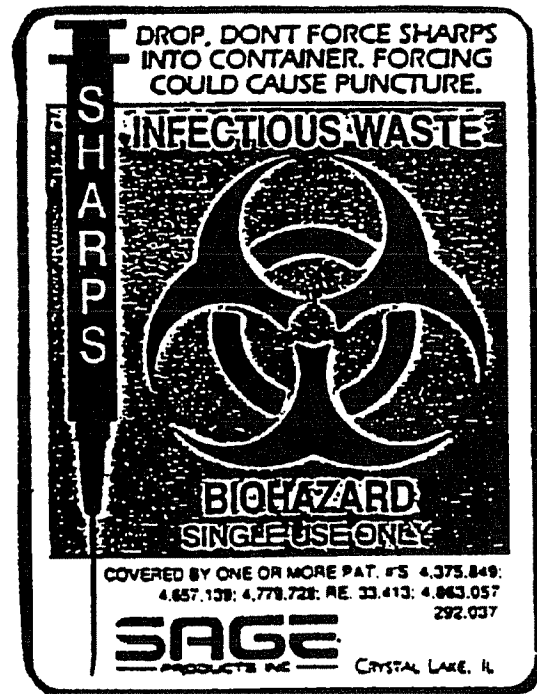


Figure 4

\*2 By its own estimate, Sage's safety campaign has been successful: "90 something percent" of the inner containers are destroyed and replaced after their first use. Hanifl Dep. 119:12-15. That some users may imprudently empty and reuse the inner containers does not, without more, create a genuine issue of material fact. The Federal Circuit has not said that a component is spent only when it is *impossible* to continue to use it. Rather, the Federal Circuit suggests that a component is spent when continued use is "neither practical nor feasible". *Everpure*, 875 F.2d at 303. Given the extremely hazardous nature of this medical waste, not to mention Sage's safety-conscious efforts to encourage disposal of filled inner containers, a reasonable jury *must* conclude that filled inner containers are spent within the meaning of *Everpure*. <sup>ENI</sup> Therefore, this Court finds that replacing inner containers is permissible repair of the '413 combination. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) ("Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no 'genuine issue for trial'."); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251 (1986) ("[T]here must be evidence on which the jury could reasonably find for [the opposing party]."). Since the hospitals are not directly infringing the '413 patent, defendants are not liable for either contributory nor

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 (Cite as: Not Reported in F.Supp.)

Page 5

induced infringement; thus, this Court GRANTS defendant's motion for partial summary judgment. *Aro*, 365 U.S. at 341; *Everpure*, 875 F.2d at 302; *Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687 (Fed. Cir. 1986).<sup>FN2</sup>

b. *Devon's Motion for Bifurcation.*

1. *Liability and Willfulness.*

To defend against Sage's charge of willful infringement, Devon intends to rely on several attorney opinion letters. See Devon's Exh. A, B, C. Devon is trapped in a catch-22, however. These letters detail Devon's tactical defenses and legal strategies. Thus, if this case is not bifurcated, Devon will be forced to either waive the attorney-client privilege early in the litigation, or retain the privilege and expose itself to a charge of willfulness. To avoid this dilemma, Devon asks this Court to separate the willfulness issue from the issues of validity and infringement under F.R.Civ.P. 42 (b), which allows bifurcation "in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy." The Federal Circuit encourages bifurcation in these cases, noting that the issue is of "great importance not only to the parties but to the fundamental values sought to be preserved by the attorney-client privilege." *Quantum Corp. v. Tandon Corp.*, 940 F.2d 642, 643-44 (Fed. Cir. 1991). See also *Fromson v. Western Litho Plate and Supply Co.*, 853 F.2d 1568, 1572 (Fed. Cir. 1988) (dicta) (suggesting that bifurcation "may be useful in meeting the attorney-client privilege problem").

\*3 A brief *in camera* review of Devon's opinion letters demonstrates that Devon does indeed face the dilemma discussed in *Quantum*. Although bifurcation may result in some duplication of effort, it will allow Devon to retain the privilege without sacrificing its willfulness defense. Therefore, this Court GRANTS Devon's motion, and orders a separate trial on the issue of willfulness.

2. *Liability and Damages.*

Devon also moves to bifurcate trial of infringement and damages. Devon argues that bifurcation of liability and damages will save effort if Devon prevails on liability, and will avoid confusing the issues. Sage responds that bifurcation will result in duplication and delay. They note that proof of

damages and liability overlap. For instance, Sage will use Devon's sales figures to prove commercial success, which in turn proves nonobviousness. These sales figures, of course, are relevant to prove Sage's damages as well.

However, since willfulness and damages can be combined into a single proceeding, bifurcating damages and liability carries little marginal cost. The overlap cited by Sage is minimal, and bifurcation will limit jury confusion and avoid needless work if Devon prevails at the liability stage. Consequently, this Court GRANTS Devon's motion to bifurcate damages and liability. Damages and willfulness will be tried together.

IV. *Conclusion*

There is no genuine issue as to the nature of inner container replacement -- it is repair, not reconstruction. Therefore, this Court GRANTS defendant's motion for partial summary judgment; defendant has not contributorily infringed or induced infringement of U.S. Patent No. Re. 33,413. Devon has also demonstrated that a separate trial of the willfulness and damage issues is appropriate; therefore, this Court GRANTS Devon's motion for bifurcation; the issue of liability for patent infringement is bifurcated from the issues of damages and willful infringement. Liability will be tried first. Discovery of Devon's opinion of counsel is stayed until further order.

IT IS SO ORDERED.

<sup>FN1</sup>. At least one recent case supports this conclusion. In *Surgical Laser Technologies, Inc. v. Surgical Laser Products, Inc.*, 25 USPQ.2d 1806 (D. Pa. 1992), plaintiff sued for infringement of its patent covering a two-piece disposable laser delivery system, used in laser surgery. Plaintiff encouraged customers to discard one of the components after surgery, thereby reducing the chance of infection. *Id.* at 1807. While it was not impossible to reuse both components of the system, the court held that replacing the delivery system was repair, not reconstruction. *Id.* at 1808-09.

<sup>FN2</sup>. Granting defendant's motion promotes public safety. If this Court held that replacing inner containers is reconstruction,

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Not Reported in F.Supp., 1994 WL 791601 (C.D.Cal.)  
(Cite as: Not Reported in F.Supp.)

Page 6

Sage would have a monopoly (albeit a legal one) over the inner container market. However, since replacing filled inner containers is permissible repair, the market for inner containers will be competitive. With competitive prices, more consumers will replace filled inner containers rather than risk emptying and reusing them.

C.D.Cal. 1994  
Sage Products, Inc. v. Devon Industries, Inc.  
Not Reported in F.Supp., 1994 WL 791601  
(C.D.Cal.)

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- [2:93cv02403](#) (Docket) (Apr. 26, 1993)

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EX. 14

1

1 IN THE UNITED STATES DISTRICT COURT

2 IN AND FOR THE DISTRICT OF DELAWARE

3 - - -

4 SMITH KLINE & FRENCH : Civil Action

5 LABORATORIES LIMITED and :  
SMITHKLINE BEECHAM :  
CORPORATION d/b/a GLAXOSMITHKLINE, :  
6 Plaintiffs, :  
7 :  
8 v. :  
9 TEVA PHARMACEUTICALS, USA, INC., :  
Defendant. : No. 05-197-GMS

10 - - -

11 Wilmington, Delaware

12 Thursday, July 28, 2005

13 9:00 a.m.

14 In Chambers

15 - - -

16 BEFORE: HONORABLE GREGORY M. SLEET, U.S.D.C.J.

17 APPEARANCES:

18 PATRICIA SHINK ROGOWSKI, ESQ.

19 Connolly Rove Lodge & Hutz LLP

20 -and-

21 AMY K. WIGMORE, ESQ.

22 Wilmer, Cutler, Pickering, Hale and Dorr LLP

23 (Washington, D.C.)

24 Counsel for Plaintiffs

25 RICHARD H. MORSE, ESQ.

Young Conaway Stargatt & Taylor, LLP

-and-

JAY P. LEFKOWITZ, ESQ., and

KAREN ROBINSON, ESQ.

Kirkland & Ellis LLP

(New York, New York)

Counsel for Defendant

2

1 THE COURT: Which side is plaintiff on?

2 MS. WIGMORE: Here. I am Amy Wigmore from

3 Wilmer, Cutler, Pickering, Hale and Dorr.

4 MS. ROGOWSKI: Good morning, Your Honor.

5 MR. MORSE: Your Honor, good morning. Karen

6 Robinson and Jay Lefkowitz.

7 THE COURT: Good morning. Nice to meet you.

8 MR. LEFKOWITZ: Good morning, Your Honor.

9 MS. ROBINSON: Good morning.

10 THE COURT: Okay. Did I see Mr. Lee's name?

11 MS. WIGMORE: He is on trial at the moment.

12 THE COURT: Will he be lead in this case?

13 MS. WIGMORE: Yes, he will.

14 THE COURT: Okay. I have looked at your joint

15 status report, preparing it. There are some differences

16 among you, or between you, as to at least when things should

17 be done, and perhaps what should be done, at least on a

18 couple of issues, or at least willfulness, I think, is a

19 bone of contention.

20 What I would like to start out by discussing is

21 the difference in the proposed timelines for completing fact

22 discovery. Plaintiff is at just about a year exactly and

23 defense is at roughly seven months or eight months, I think

24 it is.

25 MS. WIGMORE: Yes, Your Honor.

3

1 THE COURT: Why so long?

2 MS. WIGMORE: Your Honor, we believe we will

3 need a year to complete the discovery. We believe in this

4 case the burden of fact discovery is going to fall

5 disproportionately on our side because of the time periods

6 involved. The two patents at issue in the case are from

7 1984 and 1989, respectively. That is quite a long time

8 period that has elapsed. There has been no indication from

9 defendants that they are willing to limit the scope or the

10 time period of discovery.

11 Many of the individuals involved in the patents

12 at this point are former employees. There is a big

13 international side to this case, as one of the patents was

14 the result of work that was performed in England.

15 So there are many witnesses who may not be

16 employees who are located outside the country, documents

17 located outside the country.

18 In addition, we think that the scope of the

19 issues has not been there in the way that Teva has suggested

20 may be. Infringement, as far as we can tell, is still an

21 issue in the case. There will still need to be discovery in

22 on that. We believe willfulness is still an issue.

23 THE COURT: It may or may not be after today.

24 MS. WIGMORE: There has been a paragraph for

25 certification.

4

1 THE COURT: I understand that.

2 MS. WIGMORE: Obviously, they are aware of our

3 patents. The rationale and the paragraph for notice is very

4 limited for their argument of invalidity and

5 noninfringement.

6 THE COURT: What is the rationale for

7 plaintiffs' contentions that there is willful infringement

8 in light of the cases?

9 MS. WIGMORE: First of all, our case is

10 distinguishable from the Apotex case.

11 THE COURT: Merely because of Paragraph 4?

12 MS. WIGMORE: That is one reason. Also, in the

13 Apotex case, it is very clear, although in that case it is

14 not automatic that there would be willful infringement, but

15 it is certainly possible if there are extraordinary

16 circumstances present.

17 THE COURT: What might those extraordinary

18 circumstances be in an ANDA situation?

19 MS. WIGMORE: The circumstances may be basically

20 a frivolous argument for invalidity or noninfringement.

21 THE COURT: Wouldn't that go to exceptional case

22 rather than whether or not there has been willful

23 infringement, an exceptional case determination?

24 MS. WIGMORE: Well, it depends how strong the

25 argument is. If the argument that they are making is that

<p>5</p> <p>1 your patents are simply invalid because they are cobbling 2 together two pieces of prior art that we believe in no way 3 indicates invalidity, I think that is -- that could go to 4 willfulness.</p> <p>5 THE COURT: But thinking about what infringement 6 is, making, using, selling, are we really talking about 7 infringement or are we talking about attorney misconduct for 8 which they should be punished?</p> <p>9 MS. WIGMORE: I believe we are talking about 10 infringement. The Apotex case does not hold there cannot be 11 willful infringement from an ANDA filing.</p> <p>12 THE COURT: I agree.</p> <p>13 MS. WIGMORE: On those facts, the Court found 14 there could not be. If one files a Paragraph 4 15 certification, the statute is clear that that can constitute 16 infringement. If that is done with insufficient rationale, 17 where it's known that the patents exist, and that the 18 argument put together to support the notice is frivolous, we 19 believe that would constitute willful infringement.</p> <p>20 THE COURT: Why doesn't a Paragraph 4 filing 21 make this --</p> <p>22 MS. ROBINSON: Your Honor, I think Apotex and, 23 quite honestly, a recent decision, Apotex and a recent order 24 from Your Honor makes clear --</p> <p>25 THE COURT: Two days ago.</p>	<p>7</p> <p>1 whether or not the case is exceptional.</p> <p>2 THE COURT: Wouldn't it be premature for the 3 Court, though, at this point to rule out the possibility 4 that discovery might adduce evidence that might support in 5 some way a willfulness contention?</p> <p>6 MS. ROBINSON: We don't believe so, Your Honor. 7 At the moment, the best that you are going to find out is 8 the most that discovery could disclose is whether or not 9 there was a reasonable basis for the assertions made in our 10 ANDA Paragraph 4 certification.</p> <p>11 That alone wouldn't give rise to a finding of 12 willfulness. So if you include it now, it certainly would 13 assist in narrowing the issues.</p> <p>14 THE COURT: Sure would.</p> <p>15 MS. ROBINSON: It would narrow the scope of 16 discovery. To the extent that plaintiffs' discovery 17 timeline includes time to do discovery on willful 18 infringement, that certainly would cut down on the time that 19 plaintiffs contend they need.</p> <p>20 THE COURT: What is your response to that last 21 question?</p> <p>22 MS. WIGMORE: On that point I don't believe 23 there would be a significant difference in time period --</p> <p>24 THE COURT: But answer my last question. I 25 might agree with you on that. The question I posed to</p>
<p>6</p> <p>1 MS. ROBINSON: Yes. -- makes clear that the 2 Federal Circuit does not believe that a mere paper filing, 3 simply filing an ANDA, constitutes infringement, could 4 constitute willful infringement. It is technical 5 infringement in order to get the ball started for purposes 6 of litigation. But there is no making, there is no offering 7 for sale.</p> <p>8 Quite honestly, we think that Apotex makes clear 9 that the only avenue that is still available is absent some 10 actual damages. That is a separate issue. The 30-month 11 stay which runs as we actually started manufacturing the 12 product, that is a different issue.</p> <p>13 In the absence of anything other than simply 14 filing an ANDA, if there is some type of misconduct with 15 respect to whether or not you have a good-faith basis for 16 making the argument, that would put it into the exceptional 17 case.</p> <p>18 In our opinion, that is no different than a Rule 19 11 type consideration.</p> <p>20 We would say that there is no basis for willful 21 infringement based on simply filing an ANDA.</p> <p>22 Discovery misconduct again would go towards -- I 23 think that is what the Apotex case really hung its hat on, 24 discovery misconduct might be something that the Court can 25 consider. But again, that would be to the context of</p>	<p>8</p> <p>1 counsel.</p> <p>2 MS. WIGMORE: I am sorry. Which question?</p> <p>3 THE COURT: Now I have to remember it. As to 4 whether it was premature.</p> <p>5 MS. WIGMORE: I do believe it is premature, 6 because, as I mentioned before, the filing of the ANDA, the 7 Apotex case does not hold that that can't be the basis for 8 willful infringement. Here the circumstances are very 9 different. We have a Paragraph 4. The notice letter gives 10 a very, very flimsy rationale for the basis for that. I 11 think that alone can establish a prima facie case of 12 willfulness.</p> <p>13 We would then need to discover facts to further 14 bolster that claim. But I think there is enough here to go 15 forward. Just as plaintiffs here are pursuing an 16 infringement defense and, from our side, we think it's quite 17 clear that there is infringement, I think the situations are 18 very parallel. And if they are able to pursue that claim, 19 then willful infringement should certainly be something that 20 we should be able to pursue.</p> <p>21 THE COURT: Okay.</p> <p>22 I am going to side with the plaintiff on this 23 one at this stage, and suggest that this probably will, this 24 issue may well be appropriate for summary consideration. 25 Whether or not I grant permission to file other motions for</p>

9

1 summary judgment, it is likely that there will come time for  
2 us to engage that process. There are not going to be  
3 material facts in dispute. We will probably be able to take  
4 a look at it on summary judgment, at least help narrow the  
5 field for trial, if not for discovery.

6 MS. ROBINSON: Your Honor, on that issue, we  
7 might suggest that this particular issue is particularly  
8 amenable to earlier motions, dispositive motions.

9 THE COURT: Except I am not going to give you  
10 more than one round. I might otherwise agree with you.

11 I am still not convinced that you need a year  
12 for discovery in this case. You got to do a better job,  
13 counsel, to convince me than you have done so far. I  
14 understand you indicate that there are foreign entities  
15 involved. Where?

16 MS. WIGMORE: In England.

17 THE COURT: England.

18 MS. WIGMORE: There may be witnesses who have  
19 moved to other countries. But England is the primary area.

20 THE COURT: Are there any conventions that are  
21 going to have to be utilized?

22 MS. WIGMORE: I believe the Hague Convention may  
23 have to be utilized because of the former employees and  
24 perhaps other parties involved. We are still investigating  
25 that. That is certainly a possibility.

10

1 THE COURT: What is your view?

2 MS. ROBINSON: Your Honor, if we are talking  
3 discovery in London, I understand that one of the inventors  
4 on one of the patents at the time the patent issued was a  
5 British citizen, employee of GSK. You know, our position on  
6 that is, we are more than happy to travel to London. It's  
7 really no more difficult going to London than it is to go to  
8 California. And we are hopeful that we could work with  
9 plaintiff so we wouldn't have to go through the Hague  
10 Convention. This is, as I understand from plaintiffs'  
11 counsel, a former employee. We would hope that we wouldn't  
12 have to go through these extraordinary steps to get  
13 potentially an inventor to give testimony during this case.

14 I just don't think that, we don't believe that  
15 this type of discovery, this type of international discovery  
16 that's being discussed by plaintiff really is the type of  
17 discovery that requires extraordinary amounts of time to get  
18 through discovery.

19 One of the other issues, I would point out, Your  
20 Honor, is that there is four and a half months between the  
21 close of fact discovery and the close of expert discovery in  
22 plaintiffs' schedule. To the extent that that makes up a  
23 large portion of the time frame that we are talking about,  
24 we just think that that is probably more time than is really  
25 required or necessary.

11

1 THE COURT: Four and a half months between fact  
2 and expert?

3 MS. ROBINSON: Right. The completion of fact  
4 discovery would be July 28th, under plaintiffs' schedule,  
5 and the completion of expert discovery is not until November  
6 30th. I guess that's four months. That's more time than we  
7 think is really necessary. We certainly can test that.

8 THE COURT: I think what is going to drive this,  
9 as well as these considerations, the considerations of what  
10 is necessary, what is going to be necessary in terms of  
11 time, I too am convinced that the parties will likely work  
12 out matters such as with regard to inventors and people of  
13 that nature so that you won't have to go through the Hague  
14 Convention. I just not that long ago had GSK in front of  
15 me, I think there were England issues, because there always  
16 are with GlaxoSmithKline. And there was no difficulty in  
17 this regard.

18 So I am not going to factor that into my  
19 calculus in determining an appropriate amount of time for  
20 fact discovery.

21 Are there other reasons, counsel, that you think  
22 an entire year -- let me share with you, also, I am really  
23 disinclined to have this case come to trial as late as '07.  
24 This case was filed a little more than three months ago. I  
25 do disagree, based on the little bit that I admittedly have

12

1 in front of me, but I don't understand why this case would  
2 be accurately characterized as more complex than any other  
3 patent case that we have. Patent cases by definition are  
4 complex civil litigation.

5 Why is this a complex patent case.

6 MS. WIGMORE: Your Honor, I think the issue is  
7 not so much complexity as scope. Perhaps there are ways for  
8 the parties to work together to narrow the scope somewhat.  
9 One of the big concerns we have is time frame, because the  
10 patents, the applications go back to 1982. We have got no  
11 indication as of the present time that there will be any  
12 time limitation on what is being sought in discovery.

13 THE COURT: You are concerned about validity,  
14 the scope of validity?

15 MS. WIGMORE: Very much so. We have a very  
16 large corporation that has gone through multiple corporate  
17 changes, multiple employees who have come and gone. We are  
18 very concerned about being able to gather that volume of  
19 documents, particularly if we are going up to the present  
20 time and if they are going to be asking for current  
21 marketing documents and things of that nature. It is a very  
22 large burden. We want to make sure that we can get them  
23 what they are asking for in the time allotted.

24 THE COURT: The point that counsel makes is a  
25 worthy one. It causes me to say this. I don't want to have

EX. 15

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 Not Reported in F.Supp.2d, 2002 WL 1901268 (D.Del.)  
 (Cite as: Not Reported in F.Supp.2d)

Page 1

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Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court, D. Delaware.

ST. CLAIR INTELLECTUAL PROPERTY

CONSULTANTS, INC., Plaintiff,

v.

SONY CORPORATION, Sony Electronics, Inc., and

Sony Corporation of America, Defendants.

No. Civ.A.01-557-JJF.

Aug. 16, 2002.

Frederick L. Cottrell, III and Thomas H. Kovach, of Richards, Layton & Finger, Wilmington, Delaware. Ronald J. Schutz, Jake M. Holdreith, Becky R. Thorson, and Carrie M. Smith, of Robins, Kaplan, Miller & Ciresi, L.L.P., Minneapolis, Minnesota, for Plaintiff, of counsel.

Josy W. Ingersoll and Adam W. Poff, of Young Conaway Stargatt & Taylor, L.L.P., Wilmington, Delaware. Sidney David, Joseph S. Littenberg, Jonathon A. David, Jeffrey S. Dickey, and April M. Mayo, of Lerner, David, Littenberg, Krumholz & Mentlik, L.L.P., Westfield, New Jersey, of counsel.

## MEMORANDUM OPINION

FARNAN, J.

\*1 Presently before the Court is a Motion For Bifurcation Of Liability And Damages/Willfulness Issues And For A Stay Of Discovery Regarding Damages/Willfulness Issues (D.I.43) filed by Defendants Sony Corporation, Sony Electronics, Inc., and Sony Corporation of America (collectively "Sony"). For the reasons set forth below, Sony's Motion will be granted in part and denied in part.

## I. BACKGROUND

This is a patent infringement action in which Plaintiff St. Clair Intellectual Property Consultants, Inc. (hereinafter "St. Clair") alleges that Sony willfully infringes four of St. Clair's patents by manufacturing, using and selling numerous models of digital camcorders and still cameras. (D.I. 44 at 1). Sony answers these allegations by denying infringement, claiming the patents are invalid, and asserting a laches defense. Sony also asserts counterclaims,

including patent misuse and unfair competition.<sup>FN1</sup> (D.I. 44 at 1).

<sup>FN1</sup>. Originally, Sony also pleaded the defense of estoppel. (D.I. 44 at 1). However, Sony has since withdrawn this defense. (See D.I. 47 at 1).

On March 28, 2002, after discovery had commenced in this action, the Court issued a decision in Novartis Pharmaceuticals Corp v. EON Labs Mfg., Inc., 206 F.R.D. 396 (D.Del.2002). As a result of the Novartis decision, Sony filed the instant Motion (D.I.43) pursuant to Federal Rule of Civil Procedure 42(b), seeking to bifurcate the issues of damages and willful infringement from the other issues in this case.

On July 17, 2002, the Court heard argument on Sony's Motion. During the course of the argument, Sony's counsel represented that Sony intends to rely on opinions of counsel in defense of St. Clair's willfulness claim. (D.I.80). At the close of the parties' arguments, the Court denied Sony's Motion to the extent it pertains to damages, and ordered Sony's counsel to provide the opinion letters Sony intends to rely upon for an *in camera* review.<sup>FN2</sup> (D.I.80).

<sup>FN2</sup>. The Court agrees with St. Clair that Sony will not suffer any undue prejudice if the liability and damages issues are not bifurcated.

On August 1, 2002, the Court received Sony's opinion letters, as well as other related documents, and has since reviewed them. This Memorandum Opinion will address whether separation of St. Clair's willfulness claim is warranted in the circumstances of this case.

## II. DISCUSSION

Counsel for Sony contends that the discovery required by Novartis in the circumstances of this case (i.e. that Sony has elected to present a reliance on advice of counsel defense in response to St. Clair's charge of willfulness, and the fact that Sony's trial counsel authored the legal opinion relied upon) requires that the issue of willfulness be separated for

Not Reported in F.Supp.2d  
 Not Reported in F.Supp.2d, 2002 WL 1901268 (D.Del.)  
 (Cite as: Not Reported in F.Supp.2d)

Page 2

both discovery and trial. (D.I. 44 at 2-4). Specifically, Sony's counsel represents that communications occurred between Sony and its counsel which relate to issues other than willfulness as well as strategies that Sony might undertake with regard to those issues. (D.I. 44 at 2; D.I. 80). According to Sony, in the event the Court fails to separate the issue of willfulness, the disclosure of these communications to St. Clair will result in undue prejudice to Sony. (D.I. 44 at 2-4).

In response, St. Clair contends that separation of the willfulness issue is not warranted in this case. (D.I. 45 at 4). Specifically, St. Clair contends that separation would result in delay and wasteful duplication of discovery. (D.I. 45 at 11-13).

\*2 After reviewing the documents submitted by Sony, the Court finds that undue prejudice could result if these otherwise privileged documents were exchanged and used during the trial of the infringement and validity issues. Neither Sony nor St. Clair had the benefit of the Court's *Novartis* decision when Sony engaged counsel to obtain an infringement opinion. Sony and trial counsel conducted their dialogue without the knowledge that their communications on matters other than infringement could be revealed in litigation. For these reasons, the Court is sensitive to Sony's prejudice claim and will separate willfulness from the other patent issues for both discovery and trial.

### III. CONCLUSION

For the reasons set forth above, the Court will grant Sony's Motion For Bifurcation (D.I.43) to the extent it pertains to willfulness and deny Sony's Motion For Bifurcation (D.I.43) to the extent it pertains to damages.

An appropriate Order will be entered.

### ORDER

At Wilmington this 16<sup>th</sup> day of August, 2002, for the reasons set forth in the Memorandum Opinion issued this date, IT IS HEREBY ORDERED that:

1. Sony's Motion (D.I.43) to bifurcate the issue of willfulness for both discovery and trial is *GRANTED*;
2. Sony's Motion (D.I.43) to bifurcate the issue of damages is *DENIED*;
3. Discovery on the issue of willfulness is *STAYED* pending resolution of the issues of infringement,

validity, and damages.

D.Del.,2002.

St. Clair Intellectual Property Consultants, Inc. v. Sony Corp.

Not Reported in F.Supp.2d, 2002 WL 1901268 (D.Del.)

Briefs and Other Related Documents ([Back to top](#))

- [2002 WL 33029312](#) () Second Declaration of Thomas A. Gafford (Jul. 31, 2002) Original Image of this Document (PDF)
- [2002 WL 33029313](#) () Supplemental Declaration of Alexander B. Trevor (Jul. 30, 2002) Original Image of this Document (PDF)
- [2002 WL 33029311](#) () Declaration of Alexander B. Trevor (Jun. 29, 2002) Original Image of this Document (PDF)
- [1:01cv00557](#) (Docket) (Aug. 14, 2001)
- [2001 WL 34920911](#) () (Partial Testimony) (2001) Original Image of this Document (PDF)
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EX. 16

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 Slip Copy, 2006 WL 486895 (N.D.Ga.)  
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Page 1

**H**Briefs and Other Related Documents

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United States District Court, N.D. Georgia, Atlanta  
 Division.

UCB SOCIETE ANONYME, and UCB Pharma,  
 Inc., Plaintiffs,  
 v.

MYLAN LABORATORIES, INC., et al.,  
 Defendants.

No. 1:04-CV-683-WSD.

Feb. 28, 2006.

Bruce C. Haas, Ha Kung Wong, Haiyan Chen, James M. Fukuyama, Jason Johnson, Robert L. Baechtold, Scott K. Reed, Steven C. Kline, Fitzpatrick Cella Harper & Scinto, New York, NY, Emmet J. Bondurant, II, Sarah M. Shalf, Bondurant Mixson & Elmore, Atlanta, GA, for Plaintiffs.

Bruce Jefferson Boggs, Jr., Nhat Dinh Phan, Teresa Stanek Rea, Burns Doane Swecker & Mathis, Alexandria, VA, Charles J. Raubicheck, Edgar H. Haug, Jeffrey A. Hovden, Robert E. Colletti, Frommer Lawrence & Haug, New York, NY, Michael H. Imbacuan, Budd Larner, Short Hills, NJ, Stuart D. Sender, Budd Larner, Short Hills, NJ, Timothy A. Bumann, Budd Larner, Michael L. Brown, Alston & Bird, John Philip Fry, Morris Manning & Martin, C. Andrew Head, Crowley & Clarida, Atlanta, GA, Charles A. Weiss, Michael P. Hogan, Steven J. Lee, Theodore J. Chiacchio, Kenyon & Kenyon, LLP, New York, NY, Alice L. Riechers, Deanne M. Mazzochi, William A. Rakoczy, Rakoczy Molino Mazzochi Siwik, LLP, Chicago, IL, for Defendants.

*ORDER*

DUFFEY, J.

\*1 This matter is before the Court on Defendant Cobalt Pharmaceuticals, Inc.'s Rule 12(c) Motion for Judgment on the Pleadings Dismissing Plaintiffs' Willful Infringement Claims [76] and Defendants Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc.'s Rule 12(c) Motion for Judgment on the Pleadings Dismissing Plaintiffs' Willful Infringement Claims [112].

*I. BACKGROUND*

These are patent infringement actions involving UCB Societe Anonyme and UCB Pharma, Inc.'s (collectively "UCB") epilepsy drug Keppra, containing the active ingredient levetiracetam. Keppra was approved by the Food and Drug Administration ("FDA") based upon a New Drug Application ("NDA") filed by UCB. UCB holds U.S. Patent Nos. 4,837,223 (the "'223 patent") and 4,943,639 (the "'639 patent") for this drug. Defendants Cobalt Pharmaceuticals, Inc., Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively "Defendants") filed an abbreviated new drug application ("ANDA"), seeking approval by the Food and Drug Administration ("FDA") to market a generic version of Keppra.<sup>FN1</sup> In their paragraph IV certification, submitted as part of their ANDA, Defendants claim UCB's patents are invalid and will not be infringed by the generic drugs. Defendants have not yet sold their generic drug products.

<sup>FN1</sup> Congress created the ANDA procedure to allow generic drug companies to seek FDA approval for the manufacture and sale of generic drugs. Under this procedure, a company may file an ANDA for FDA approval to market a generic version of a previously-approved new drug application, notifying the patent holder of the ANDA application. After such filing, a district court has jurisdiction under 35 U.S.C. § 271(e)(2) for a patent-infringement action before the ANDA drug has been marketed to determine if the patent is valid and if the generic drug would infringe the patent. An ANDA applicant must address patents covering the drug by filing one of four certifications. See 21 U.S.C. § 355(j)(2)(A)(i)-(iv). Defendants here filed a "paragraph IV certification," stating UCB's patents are invalid or will not be infringed by the generic drug.

In response to Defendants' filing of an ANDA and paragraph IV certification, UCB sued Defendants for infringement of its patents. UCB claims Defendants' "statement of the factual and legal bases for its opinion regarding the validity" of the patents "is devoid of an objective good faith basis in either the

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Page 2

facts or the law.” (Mylan Compl. ¶¶ 26-27, 43-44; Cobalt Compl. ¶¶ 25, 42.) As a result, UCB claims Defendants are liable for willful infringement of its patents, and that this case is “exceptional.”

Defendants move the Court to enter judgment on the pleadings dismissing UCB's willful infringement claims pursuant to Federal Rule of Civil Procedure 12(c). Defendants claim UCB's sole basis for these claims—that Defendants filed an ANDA and a baseless paragraph IV certification—is insufficient to support its claims of willful infringement.

## II. DISCUSSION

“A motion for judgment on the pleadings is subject to the same standard as is a Rule 12(b)(6) motion to dismiss.” Provident Mut. Life Ins. Co. of Philadelphia v. City of Atlanta, 864 F.Supp. 1274, 1278 (N.D.Ga.1994). On a motion for judgment on the pleadings, the allegations contained in the complaint must be accepted as true and the facts and all inferences must be construed in the light most favorable to the nonmoving party. See Hawthorne v. Mac Adjustment, Inc., 140 F.3d 1367, 1370 (11th Cir.1998). A “complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.” Conley v. Gibson, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957).

\*2 Because UCB's only basis for its claims of willful infringement is that Defendants filed an allegedly baseless ANDA and paragraph IV certification, Defendants argue that UCB's allegations cannot support a claim for willful infringement and must be dismissed under Rule 12(c). Defendants claim the ANDA procedure is an artificial act of infringement, created by Congress, to allow parties to litigate patent infringement claims before the generic manufacturer actually markets the generic drugs. Recognizing the artificial nature of such infringement, Defendants claim the Federal Circuit has held the mere filing of an ANDA application and certification cannot support a claim for willful infringement. (Def. Cobalt's Mot. for J. on Pleadings at 7; Mylan Defs.' Mot. for J. on Pleadings at 5.) See also Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1350-51 (Fed.Cir.2004); Aventis Pharma Deutschland GMBH v. Cobalt Pharms., Inc., 355 F.Supp.2d 586 (D.Mass.2005).<sup>FN2</sup>

<sup>FN2</sup>. Defendants Cobalt and Mylan filed notices of filing additional authority [140, 154, 155], citing two additional cases in which district courts dismissed willful infringement claims in similar cases.

UCB argues it alleges Defendants were “aware of the '223 and '639 patents when it filed its ANDA.” (UCB's Opp'n to Def. Cobalt's Mot. for J. on Pleadings at 7.) UCB further alleges Defendants' statements regarding the factual and legal bases for their opinion regarding the validity of the patents are “devoid of an objective good faith basis in either the facts or the law,” and UCB's willful infringement claim “is based on Cobalt's wholly unjustified assertions in its certification letter, its failure to satisfy its obligations of due care, and its reliance on those arguments in this litigation.” (*Id.*)<sup>FN3</sup>

<sup>FN3</sup>. UCB also contends the Court may award attorneys' fees under the “exceptional case” standard based on the totality of the circumstances, with or without a finding of willful infringement. (UCB's Opp'n to Def. Cobalt's Mot. for J. on Pleadings at 8 (citing Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1346-47 (Fed.Cir.2000).) UCB argues the Federal Circuit held “the [Hatch-Waxman] Act unambiguously permits an award of attorney fees to the prevailing party in exceptional cases on the basis of an ANDA filing.” (*Id.*) An award of attorneys' fees upon a finding that a case is “exceptional” is to be distinguished from a finding of willful infringement. See Glaxo, 376 F.3d at 1350 (“[I]n Yamanouchi, we did not agree that the generic company had engaged in willful infringement, but rather determined that an award of attorney's fees was permitted because ... unjustified litigation and misconduct has always justified a finding of an exceptional case.”).

The issue before the Court is whether UCB can base its claims of willful infringement on its allegations that Defendants filed an ANDA and objectively baseless paragraph IV certifications. Glaxo is the controlling authority on this issue. In Glaxo, the district court found defendant's filing of an ANDA without a reasonable basis for believing its product would not infringe the patent constituted an act of willful infringement, and awarded plaintiff attorneys' fees. The Federal Circuit reversed the district court's

Slip Copy  
 Slip Copy, 2006 WL 486895 (N.D.Ga.)  
 (Cite as: Slip Copy)

Page 3

award of attorneys' fees. The court found that filing an ANDA was a "highly artificial" act of infringement, giving "rise to only a limited set of statutorily-defined consequences set forth in 35 U.S.C. § 271(e)(4)." *Glaxo*, 376 F.3d at 1349. The court stated, "as suggested by *Yamanouchi*, we now hold that the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)." *Glaxo*, 376 F.3d at 1350-51. <sup>FN4</sup>

<sup>FN4</sup>. The court expressly held that attorneys' fees may be awarded to the prevailing party in "exceptional cases" pursuant to 35 U.S.C. § 285, and that the filing of a baseless paragraph IV certification in an ANDA filing, "when combined with litigation misconduct, warranted an exceptional case finding." *Glaxo*, 376 F.3d at 1350 (citing *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1346 (Fed.Cir.2000)).

In this case, the only act of infringement alleged in UCB's complaint is Defendants' filing of an ANDA and an allegedly baseless paragraph IV certification. The Federal Circuit has spoken clearly on this issue. Applying *Glaxo* to the facts of this case, and viewing the allegations as true and in the light most favorable to UCB, UCB's allegations cannot support a claim of willful infringement. Accordingly, Defendants are entitled to judgment on the pleadings on UCB's claims for willful infringement. <sup>FN5</sup> *Accord Aventis Pharma Deutschland GMBH v. Cobalt Pharms, Inc.*, 355 F.Supp.2d 586, 592 (D.Mass.2005) (granting defendant's motion for judgment on the pleadings on plaintiffs' willful infringement claim).

<sup>FN5</sup>. Defendants' filing of a baseless ANDA certification may permit an award of attorneys' fees as part of a finding that this case is exceptional. See *Yamanouchi*, 231 F.3d at 1347 (noting the "trial court need not have elevated the ANDA certification into a finding of willful infringement," but finding "a case initiated by a paragraph (2) filing, like any other form of infringement litigation, may become exceptional if the ANDA filer makes baseless certifications"); *Aventis Pharma Deutschland GMBH v. Lupin*, No. 2:05CV421, 2006 WL 141670, at \*6 (E.D.Va. Jan. 18, 2006) ("[A] district

court may not 'elevate' an ANDA certification, *even if it is "baseless,"* into a finding of willful infringement for the purposes of attorney's fees; rather, a baseless ANDA certification accompanied by litigation misconduct may result in an award of attorney's fees because such conduct constitutes an 'exceptional case.' ").

### III. CONCLUSION

\*3 For the reasons state above,

IT IS HEREBY ORDERED that Defendant Cobalt Pharmaceuticals, Inc.'s Rule 12(c) Motion for Judgment on the Pleadings Dismissing Plaintiffs' Willful Infringement Claims [76] and Defendants Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc.'s Rule 12(c) Motion for Judgment on the Pleadings Dismissing Plaintiffs' Willful Infringement Claims [112] are GRANTED.

SO ORDERED.

N.D.Ga., 2006.

UCB Societe Anonyme v. Mylan Laboratories, Inc.  
 Slip Copy, 2006 WL 486895 (N.D.Ga.)

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Slip Copy  
 Slip Copy, 2006 WL 486895 (N.D.Ga.)  
 (Cite as: Slip Copy)

Page 4

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Slip Copy  
Slip Copy, 2006 WL 486895 (N.D.Ga.)  
(Cite as: Slip Copy)

Page 5

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END OF DOCUMENT

EX. 17

## Westlaw.

Not Reported in F.Supp.  
 Not Reported in F.Supp., 1994 WL 74989 (N.D.Ill.)  
 (Cite as: Not Reported in F.Supp.)

Page 1

**H**Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court, N.D. Illinois, Eastern  
 Division.  
 UNITED STATES GYPSUM COMPANY, Plaintiff,  
 v.  
 NATIONAL GYPSUM COMPANY, Defendant.  
 No. 89 C 7533.

March 10, 1994.

## MEMORANDUM OPINION AND ORDER

PLUNKETT, District Judge.

\*1 The facts of the case are extensively set out in an earlier Opinion, *see United States Gypsum v. National Gypsum Co.*, No. 89 C 7533 (N.D.Ill. Jan. 27, 1993) (Plunkett, J.), and we need not restate them herein. Suffice it to say that USG sued National for infringement of two patents involving lightweight joint compound. National filed a Counterclaim alleging that USG's enforcement of the patents was a bad faith attempt to interfere with National's business relationships in violation of antitrust laws. After years of litigation and at least four Memorandum Opinion and Orders from this court, this case is finally ready to try, and is before us once again today so that we may decide how we will proceed at trial.

Plaintiff USG argues that we should bifurcate the trial of the patent infringement from the antitrust counterclaims. Defendant National, on the other hand, argues that bifurcation of the antitrust and patent issues will result in needless duplication of evidence and will not necessarily result in saving any trial time. National also argues that a separate trial of the damages phase is the norm that should be followed in the present case. USG opposes that suggestion because it anticipates presenting its proof of damages in a short and uncomplicated fashion.

*Discussion*

Rule 42(b) of the Federal Rules of Civil Procedure states, in pertinent part:

The court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy, may order a separate trial of any claim, crossclaim, counterclaim or third-party

claim, or of any separate issue or of any number of claims ... always preserving inviolate the right of trial by jury....

Fed.R.Civ.P. 42(b). The question of bifurcation, or, as in this case, trifurcation, is to be decided by the trial court on a case-by-case basis. *Lis v. Robert Packer Hosp.*, 579 F.2d 819, 824 (3d Cir.), cert. denied, 439 U.S. 955 (1978); *PPG Indus. v. Libbey-Owens-Ford Co.*, No. 90 C 6067, slip op. at 2 (N.D.Ill. Sept. 23 1992) (Marovich, J.); *Avia Grp. Int'l v. Nike*, 22 U.S.P.Q.2d 1475, 1476 (D.C.Or.1991). The trial court's discretion here is broad, and is guided by its sense of what format will "be conducive to the promotion of judicial economy and the avoidance of prejudice." *PPG*, slip op. at 2 (citing *Naxon Telesign Corp. v. GTE Info. Sys.*, 89 F.R.D. 333, 341 (N.D.Ill.1980)). Though the court should not routinely order separate trials, "issues of validity, title, infringement, and damages in patent and copyright cases may be separately tried unless this course will inconvenience the court or seriously prejudice the rights of some of the parties." *PPG*, id. (quoting *Swofford v. B. & W.*, 34 F.R.D. 15 (S.D.Tex.1963), aff'd, 336 F.2d 406 (5th Cir.1964), cert. denied, 379 U.S. 962 (1965)). However, the major consideration is which choice is "most likely to result in a just final disposition of the litigation." *In re Innotron Diag.*, 800 F.2d 1077, 1084 (Fed.Cir.1986) (citing 9 Charles Wright & Arthur Miller, *Federal Practice and Procedure*, § 2388 (1971)).

\*2 As to the bifurcation of the patent infringement from the antitrust trial, it is common practice to bifurcate these issues so that the complex antitrust issues are reached only if a showing of fraud, necessary to a *Walker Process* antitrust recovery, is still tenable after litigating the issue of inequitable conduct in procuring the patent:

Deferral of trial on antitrust issues, with their additional requirements of proof of the various elements of an antitrust violation and of injury to the complaining party, would be likely in many cases to lead to a complete avoidance of a complex antitrust trial by settlement after trial of the patent issues, as in *Walker Process*.

James B. Pegram, *Separate Trial in Patent-Antitrust and Patent-Unenforceability Litigation*, 64 F.R.D. 185, 200 (footnotes omitted). See also *Innotron*, 800

Not Reported in F.Supp.  
 Not Reported in F.Supp., 1994 WL 74989 (N.D.Ill.)  
 (Cite as: Not Reported in F.Supp.)

Page 2

F.2d at 1084 (bifurcating patent and antitrust trials is "now standard practice").

We feel that bifurcation of the quite complex, and at this point, contingent, antitrust trial from the patent issues, in accordance with the general practice, best serves the interests of justice in this case. Though, as National points out, there is a degree of overlap between the evidence as to inequitable conduct element in their invalidity defense on USG's infringement claim and the common law fraud element in their *Walker Process* counterclaim, should the patents be found valid and enforceable in the patent trial, a motion for a directed verdict on the Defendant's *Walker Process* counterclaims may be in order. See, e.g. FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1417 (Fed.Cir.1987) ("FMC's failure to establish inequitable conduct precludes a determination that it had borne its greater burden of establishing the fraud required to support its *Walker Process* claim."). See also Hewlett Packard Co. v. Bausch & Lomb, 882 F.2d 1556, 1563 (Fed.Cir.1989) (noting that an "extremely high level of misconduct, actual fraud, is necessary to sustain a *Walker Process* claim ..."), *cert. denied*, 493 U.S. 1076 (1990).

As to the question of separating liability from willfulness, we also feel bifurcation is called for. See Pittway Corp. v. Maple Chase Co., No. 91 C 3582, 1992 WL 392584, 1992 U.S.Dist. LEXIS 19237, \*16 (N.D.Ill. Dec. 15, 1992) (Zagel, J.) (bifurcating liability and willfulness). National points out that, if these issues are not separated, it is faced with the unpleasant choice of either waiving its attorney-client privilege as to documents it hopes to use to defend itself on the willfulness question, or retaining the privilege to keep the documents out on the liability issue. If both issues are tried together, National will either be deprived of a colorable defense to the willfulness claim or be damaged by the admissions in those documents in the liability phase. That is an untenable situation. See Quantum Corp. v. Tandon Corp., 940 F.2d 642, 643-44 (Fed.Cir.1991) (court recognizes the problem, and, in *dicta*, suggests that "[t]rial courts thus should give serious consideration to a separate trial on willfulness whenever the particular attorney-client communications ... reveal that the defendant is confronted with this dilemma.")

\*3 Aside from the willfulness issue, however, we do not believe damages should be bifurcated. The Plaintiff has represented to us that they do not expect to take more than a day to put their damages case in evidence. Where, as here, the damages case is not

overly complex or extensive, there is no need to bifurcate. See, e.g., *Output Tech. Corp. v. Data Prod. Corp.*, 22 U.S.P.Q.2d 1072 (W.D.Wash.1991) (bifurcation of damages denied in two-week trial where damages were not expected to take more than a day to present).

### Conclusion

For the reasons stated above, we "trifurcate" this trial into patent liability, willfulness, and antitrust phases.

N.D.Ill., 1994.  
 U.S. Gypsum Co. v. National Gypsum Co.  
 Not Reported in F.Supp., 1994 WL 74989 (N.D.Ill.)

Briefs and Other Related Documents ([Back to top](#))

• [1:89cv07533](#) (Docket) (Oct. 05, 1989)

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